CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125196

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

Date:	April 3, 2008
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From:	Laura Pincock, Pharm.D., Safety Evaluator Division of Medication Errors and Technical Support
Subject:	Final Name Review of PegIntron/Rebetol Combo Pack
Drug Name(s):	PegIntron/Rebetol Combo Pack
Submission Number:	
Application Type/Number:	BLA 125196/0
Applicant/sponsor:	Schering Corporation
OSE RCM #:	2007-2543

CONTENTS

EXECUTIVE SUMMARY

The results of the Proprietary Name Risk Assessment found that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors, ***provided that*** the other proposed (but not yet approved) proprietary name, [redacted] is not approved. However, it appears that the approval decision for [redacted] is scheduled after the action date for PegIntron/Rebetol Combo Pack. If PegIntron/Rebetol Combo Pack is approved first, DMETS will recommend that the second product, [redacted], seek an alternate name. Thus at this time, DMETS has no objections to the use of the proprietary name, PegIntron/Rebetol Combo Pack.

In addition, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMETS rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. Additionally, if the product approval is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

1 BACKGROUND

PegIntron/Rebetol Combo Pack is the proprietary name for the proposed product, a co-packaged kit containing the PegIntron Redipen single-dose delivery system (Peg-interferon alfa-2b) and Rebetol (Ribavirin, USP) capsules.

The Division of Antiviral Products submitted a request on June 28, 2006, for DMETS to assess the proposed tradename, [redacted] for the co-packaged product of PegIntron (Peginterferon alfa-2b Powder for Injection) and Rebetol (Ribavirin, USP) Capsules. In a memorandum dated August 31, 2006 (OSE Consult # 06-0215), DMETS objected to this name [redacted] Specifically, the name [redacted]

The Sponsor submitted an alternate proprietary name, PegIntron/Rebetol Combo Pack. DMETS reviewed the proposed name, PegIntron/Rebetol Combo Pack in a name review dated November 20, 2006 (OSE Consult # 2006-744). In that review, DMETS had no objections to the use of the proprietary name. However, DMETS was concerned that the proposed name, PegIntron/Rebetol Combo Pack, is very long and may be abbreviated to fit various prescribing and dispensing systems. DMETS was concerned that such abbreviations may pose a problem. However, DMETS was unable to ascertain what abbreviations might be used and thus were unable to evaluate the potential problems that this name might pose. Thus, DMETS recommended that the Applicant be made aware of the likelihood that abbreviations will be used, and that they should take steps to reduce the potential for the name to be abbreviated.

DMETS reviewed the proposed package insert, labels, and labeling for PegIntron/Rebetol Combo Pack in a consult dated November 20, 2006 (OSE Consult #2006-174).

1.1 INTRODUCTION

This review was written in response to a request from the Division of Antiviral Products to re-evaluate the proposed name for its potential to contribute to medication errors. The proposed proprietary name, PegIntron/Rebetol Combo Pack, is evaluated to determine if the name could be potentially confused with other proprietary or established drug names.

1.2 PRODUCT INFORMATION

PegIntron/Rebetol Combo Pack is a co-packaged kit containing the PegIntron Redipen single-dose delivery system (Peg-interferon alfa-2b) and Rebetol (Ribavirin, USP) capsules. PegIntron is a prescription covalent conjugate of recombinant alfa-2b interferon with monomethoxy polyethylene glycol (PEG). Ribavirin is a prescription nucleoside analog. PegIntron/Rebetol Combo Pack is indicated for the

treatment of chronic hepatitis C in patients with compensated liver disease who have not been previously treated with interferon alpha and are at least 18 years of age. The recommended dose of PegIntron is 1.5 mcg/kg/week in combination with 800-1400 mg Rebetol daily based on patient body weight.

There are five proposed co-packaged strengths of PegIntron/Rebetol Combo Pack. Each package consists of a carton containing four PegIntron Redipen units, each containing one B-D needle and two alcohol swabs, and two bottles of Reberol capsules. Each package contains a four week supply, or enough for 28 days of treatment. The package should be stored in the refrigerator (2° to 8° C). When separated, the Rebetol Capsules may be stored at room temperature, but the PegIntron Redipen should still be refrigerated at 2° to 8° C.

Table 1. The five PegIntron/Rebetol Combo Pack Packages (each contains 4 week supply):

Four PegIntron 50 mcg/0.5 mL Redipen Units	Two bottles of 56-count Rebetol 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs
Four PegIntron 80 mcg/0.5 mL Redipen Units	Two bottles of 56-count Rebetol 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs
Four PegIntron 120 mcg/0.5 mL Redipen Units	Two bottles of 70-count Rebetol 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs
Four PegIntron 150 mcg/0.5 mL Redipen Units	Two bottles of 84-count Rebetol 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs
Four PegIntron 150 mcg/0.5 mL Redipen Units	Two bottles of 98-count Rebetol 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs

2 METHODS AND MATERIALS

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

For the proprietary name, PegIntron/Rebetol Combo Pack, the medication error staff of DMETS search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2).

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 detail 2.1.4). The overall risk assessment is based on the findings of a Failure Modes 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. [1] FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. DMETS 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. [2]

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[1] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

[2] National Coordinating Council for Medication Error Reporting and Prevention. http://www.nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

DMETS uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed drug name include, but are not limited to established name of the proposed product, the proposed indication, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMETS 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.[3]

2.1 PROPRIETARY NAME RISK ASSESSMENT

2.1.1 Search Criteria

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

To identify drug names that may look similar to PegIntron/Rebetol Combo Pack, the Staff also considers the other orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (letters and number of words), upstrokes ('I', 't', 'b', 't', 'l', 'k'), capital letters ('P', 'I', 'R', 'C', 'P'), downstokes ('g') cross-strokes ('t', 't'), and dotted letters (none). Additionally, one letter in PegIntron may be vulnerable to ambiguity when scripted, as the lower case letter 'g' may appear as 'y'. As such, the Staff also considers these alternate appearances when identifying drug names that may look similar to PegIntron/Rebetol Combo Pack.

When searching to identify potential names that may sound similar to PegIntron/Rebetol Combo Pack, the Medication Error Staff search for names with similar stresses (Com-BO-pack or COM-bo-pack), and placement of vowel and consonant sounds. The Sponsor's intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

The Staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting For this review, the Medication Error Staff were provided with the following information about the proposed product: the proposed proprietary name (PegIntron/Rebetol Combo Pack), the established name (Peg-interferon alfa-2b Powder for Injection and Ribavirin, USP capsules), proposed indication (treatment of chronic hepatitis C in patients with compensated liver disease), strength (see Table 1 in section 1.2), dose (PegIntron 1.5 mcg/kg/week in combination with 800-1400 mg Rebetol daily based on patient body weight), frequency of administration (PegIntron-once weekly; Rebetol- divided doses typically twice daily), route (PegIntron-subcutaneous; Rebetol-oral) and dosage form of the product (PegIntron-injection; Rebetol-capsule).

[3] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Appendix A provides a more detailed listing of the product characteristics the Medication Error Staff general take into consideration.

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

2.1.2 Data base and information sources

The proposed proprietary name, PegIntron/Rebetol Combo Pack, was provided to the medication error staff of DMETS to conduct a search of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to PegIntron/Rebetol Combo Pack using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, the Medication Error Staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the Medication Error Staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

2.1.3 CDER Expert Panel Discussion

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

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

2.2 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.[4] When applying FMEA to assess the risk of a proposed proprietary name, DMETS seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective then remedies available in the post-approval phase.

[4] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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 PegIntron/Rebetol Combo Pack 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 PegIntron/Rebetol Combo Pack 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 posses 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.

DMETS will object to the use of proposed proprietary name when the 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. DMETS 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. Medication Error Staff identify a potential source of medication error within the proposed proprietary name. The proprietary name may be misleading, or inadvertently introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug another drug product.

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

If none of these conditions are met, then DMETS will not object to the use of the proprietary name. If any of these conditions are met, then DMETS will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Sponsor; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the IOM, WHO, JCAHO, and ISMP, 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, DMETS contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken in the past; but at great financial cost to the Sponsor, and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for the approving the error-prone proprietary name. Moreover, even after Sponsor's 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, DMETS believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval (see limitations of the process).

If DMETS 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. DMETS is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMETS 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 DMETS may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

3 RESULTS

3.1 DATA BASE AND INFORMATION SOURCES

DMETS conducted a search of the internet, several standard published databases and information sources (see Section 7 References) for existing drug names which sound-alike or look-alike to PegIntron/Rebetol Combo Pack to a degree where potential confusion between drug names could occur and result in medication errors in the usual clinical practice settings. Since our last review, 1 additional name was identified as having some similarity to the name PegIntron/Rebetol Combo Pack.

One additional name ([redacted] was thought to look and sound similar to PegIntron/Rebetol Combo Pack.

3.2 CDER EXPERT PANEL DISCUSSION

The Expert Panel noted one name, [redacted], thought to have both orthographic and phonetic similarity to PegIntron/Rebetol Combo Pack and have the potential for confusion. DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.2.1 Safety evaluator risk assessment

Independent searches by the primary Safety Evaluator identified no additional names, other than [redacted], thought to look similar to PegIntron/Rebetol Combo Pack and represent a potential source of drug name confusion. As such, one name was analyzed to determine if the drug name could be confused with PegIntron/Rebetol Combo Pack and if the drug name confusion would likely result in a medication error.

The proposed name identified, [redacted], was determined to have some orthographic and/or phonetic similarity to PegIntron/Rebetol Combo Pack, and thus determined to present some risk for confusion. Failure modes and effects analysis was then applied to determine if the proposed name, PegIntron/Rebetol Combo Pack, could potentially be confused with [redacted] and lead to medication error.

However, DMETS notes that [redacted] is not yet FDA approved.

4 DISCUSSION

The results of the Proprietary Name Risk Assessment found that the proposed name, PegIntron/Rebetol Combo Pack, has some similarity to other proprietary and established drug names, but the findings of the FMEA indicates that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors, in the current marketplace.

For the name, [redacted], FMEA determined that medication errors were possible because the name [redacted] is included in the name PegIntron/Rebetol Combo Pack. Additionally, errors are possible because the products overlap in dose and one of the active ingredients, [redacted] Furthermore, both proposed products will be used for the same indication and patient population. Refer to Appendix B for the results of the FMEA.

Moreover, DMETS notes that in our previous review of the proposed name, PegIntron/Rebetol Combo Pack, dated November 20, 2006 (OSE Consult # 2006-744), DMETS had no objections to the use of the proprietary name but was concerned that the proposed name, PegIntron/Rebetol Combo Pack, was very long and may be abbreviated to fit various prescribing and dispensing systems. DMETS was concerned that such abbreviations may pose a problem. However, DMETS was unable to ascertain what abbreviations might be used and thus were unable to evaluate the potential problems that this name might pose. Therefore at that time, DMETS recommended that the Applicant be made aware of the likelihood that abbreviations will be used, and that they should take steps to reduce the potential for names to be abbreviated. However, DMETS notes that at this time, it would be possible for the name 'Combo Pack' or some similar abbreviation thereof, to be used as an abbreviation for PegIntron/Rebetol Combo Pack, further increasing the potential for confusion and medication errors with the second proposed product, [redacted] Given these risks, DMETS recommends that whichever product is awarded approval first has the right to use the name, and the second product should seek an alternate name.

The findings of the Proprietary Name Risk Assessment are based upon current understanding of factors that contribute to medication errors involving name confusion. Although we believe the findings of the Risk Assessment to be robust, our findings do have limitations. First, because our assessment involves a

limited number of practitioners, it is possible that the analysis did not identify a potentially confusing name. Also, there is some possibility that our Risk Assessment failed to consider a circumstance in which confusion could arise. However, DMETS believes that these limitations are sufficiently minimized by the use of an Expert Panel.

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

Overall, our Risk Assessment is limited by our current understanding of medication errors and causality. The successful application of Failure Modes and Effect Analysis depends upon the learning gained for a spontaneous reporting program. It is quite possible that our understanding of medication error causality would benefit from unreported medication errors; and, that this understanding could have enabled the Staff to identify vulnerability in the proposed name, packaging, and labeling that was not identified in this assessment. To help minimize this limitation in future assessments, we encourage the Sponsor to provide the Agency with medication error reports involving their marketed drug products regardless of adverse event severity.

5 CONCLUSIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, PegIntron/Rebetol Combo Pack, does not appear to be vulnerable to name confusion that could lead to medication errors in the current marketplace. However, FDA is currently reviewing another product with the proposed name [redacted] Should both names be approved, the potential for medications errors to occur is greatly increased. Therefore, whichever product is awarded approval first has the right to use the name, and DMETS recommends that the second product seek an alternate name (see Appendix B). It appears that the approval decision for [redacted] is scheduled after the action date for PegIntron/Rebetol Combo Pack. If PegIntron/Rebetol Combo Pack is approved first, DMETS will recommend that the second product, [redacted], seek an alternate name. Thus at this time, DMETS does not object to the use of the proprietary name, PegIntron/Rebetol Combo Pack, for this product. However, if **any** of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMETS rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. If 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. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

6 RECOMMENDATIONS

A. DMETS does not object to the use of the proprietary name, PegIntron/Rebetol Combo Pack, for this product ***provided that*** the other proposed (but not yet approved) proprietary name, [redacted] is not approved before this application. In the event that the other application is awarded approval first, DMETS recommends that the second product seek an alternate name.

B. If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMETS rescinds this Risk Assessment finding, and recommends that the proposed name be resubmitted for review.

C. If the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

7 REFERENCES

1. Adverse Events Reporting System (AERS)

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

2. Micromedex Integrated Index (http://weblern/)

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

3. Phonetic and Orthographic Computer Analysis (POCA)

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

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

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

5. AMF Decision Support System [DSS]

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

6. Division of Medication Errors and Technical Support proprietary name consultation requests

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

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

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

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

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

9. WWW location http://www.uspto.gov.

Provides information regarding patent and trademarks.

10. Clinical Pharmacology Online (http://weblern/)

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

11. Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at www.thomson-thomson.com

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

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

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

13. Stat!Ref (http://weblern/)

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

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

List contains all the recognized USAN stems.

15. Red Book Pharmacy's Fundamental Reference

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

16. Lexi-Comp (www.pharmacist.com)

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

17. Medical Abbreviations Book

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

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

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

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstokes Downstrokes Cross-stokes Dotted letters	• Names may look similar when scripted, and lead to drug name confusion in written communication

		Ambiguity introduced by scripting letters Overlapping product characteristics	
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	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Appendix B: Potential confusing name with numerical overlap in strength or dose

Failure Mode: Name confusion	**Causes (could be multiple)**	**Effects**
PegIntron/Rebetol Combo (Peg-interferon alfa-2b Powder for Injection and Ribavirin, USP capsules)	**See Table 1 for complete package contents**	**Usual dose: PegIntron 1.5 mcg/kg/week in combination with 800-1400 mg Rebetol based on patient body weight divided into twice daily doses.**
[redacted]	Orthographic similarity Phonetic similarity Potential abbreviation of name(s) Numeric overlap in dose (increments of [redacted]	Medication error unlikely to occur given that [redacted] is a proposed name for a product that is not yet approved. However, should both names be approved, the potential for medication errors to occur is greatly increased. *Rationale*: The name [redacted] is included in the name PegIntron/Rebetol Combo Pack. An order for either product could be misinterpreted and filled with a subset of drugs or combination of drugs other than what the prescriber intended. A prescription order for either product will likely contain [redacted]

	[redacted] Hospital substitution of individual active components if package is not formulary	products. These products [redacted] therefore, prescribers and pharmacists will not likely question a patient presenting prescriptions for either one based on previous prescription history. It appears that the approval decision for [redacted] is scheduled after the action date for PegIntron/Rebetol Combo Pack. If PegIntron/Rebetol Combo Pack is approved first, DMETS will recommend that the second product, [redacted], seek an alternate name.

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; WO22, Mail Stop 4447)

DATE RECEIVED:	**DESIRED COMPLETION DATE:**	**OSE REVIEW #:** 2006-744
November 1, 2006	January 31, 2007	
DOCUMENT DATE:		
October 16, 2006	PDUFA DATE: May 7, 2007	

TO: Debra Birnkrant, M.D., Director
Division of Antiviral Products

THROUGH: Nora Roselle, Pharm.D., Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, R.Ph., Director
Division of Medication Errors and Technical Support

FROM: Laura L. Pincock, Pharm.D., Safety Evaluator
Division of Medication Errors and Technical Support

PRODUCT NAME: **PegIntron/Rebetol Combo Pack** containing:

PegIntron Redipen
(Peginterferon alfa-2b)
Powder for Injection
and
REBETOL
(Ribavirin, USP) Capsules, 200 mg

BLA #: 125196/0
BLA SPONSOR: Schering Corporation

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, PegIntron/Rebetol Combo Pack. However, DMETS is concerned that the proposed name, PEGIntron/Rebetol Combo Pack, is very long and may be abbreviated to fit various prescribing and dispensing systems. DMETS is concerned that such abbreviations may pose a problem. However, DMETS is unable to ascertain what abbreviations may be used. Thus we are unable to evaluate the potential problems that abbreviations of this name might pose. DMETS recommends that the Sponsor be made aware of the likelihood that abbreviations will be used, and they should take steps to reduce the potential for the name to be abbreviated (See Section III). This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.

2. DDMAC finds the proprietary name "PegIntron/Rebetol Combo Pack" acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Tanya Clayton, Project Manager, at 301-796-0871.

Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
White Oak 22, Mail Stop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME, LABEL, AND LABELING REVIEW

DATE OF REVIEW: December 4, 2006

BLA# 125196/0

NAME OF DRUG: **PegIntron/Rebetol Combo Pack** containing:

PegIntron Redipen
(Peginterferon alfa-2b)
Powder for Injection
and
REBETOL
(Ribavirin, USP) Capsules, 200 mg

BLA SPONSOR: Schering Corporation

I. INTRODUCTION:

The Division of Antiviral Products submitted a request on June 28, 2006, for DMETS to assess the proposed tradename, [redacted] for the co-packaged product of PegIntron (Peginterferon alfa-2b) and Rebetol (Ribavirin, USP) Capsules. In a memorandum dated August 31, 2006 (OSE Consult # 06-0215), DMETS objected to this name [redacted] Thus, the Sponsor has submitted this alternate proprietary name, PegIntron/Rebetol Combo Pack. DMETS reviewed the proposed package insert, labels, and labeling for PegIntron/Rebetol Combo Pack in a previous consult dated November 20, 2006 (OSE Consult #2006-174), thus this review will focus only on the proposed proprietary name.

PRODUCT INFORMATION

PegIntron/Rebetol Combo Pack is a co-packaged kit containing the PegIntron Redipen single-dose delivery system (Peg-interferon alfa-2b) and REBETOL (Ribavirin, USP) capsules. PegIntron is a prescription covalent conjugate of recombinant alfa-2b interferon with monomethoxy polyethylene glycol (PEG). Ribavirin is a prescription nucleoside analog. PegIntron/Rebetol Combo Pack is indicated for the treatment of chronic hepatitis C in patients with compensated liver disease who have not been previously treated with interferon alpha and are at least 18 years of age. The recommended dose of PegIntron is 1.5 mcg/kg/week in combination with 800-1400 mg REBETOL based on patient body weight.

There are five co-packaged strengths of PegIntron/Rebetol Combo Pack available. Each package consists of a carton containing four PegIntron Redipen units, each containing one B-D needle and two alcohol swabs, and two bottles of REBETOL capsules. The package should be stored in the refrigerator (2° to 8° C). When separated, the REBETOL Capsules may be stored at room temperature, but the PegIntron Redipen should still be refrigerated at 2° to 8° C.

There are five PEGINTRON/REBETOL COMBO PACK Packages available:		
Four PegIntron 50 mcg/0.5 mL Redipen Units	Two bottles of 56-count REBETOL 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs
Four PegIntron 80 mcg/0.5 mL Redipen Units	Two bottles of 56-count REBETOL 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs
Four PegIntron 120 mcg/0.5 mL Redipen Units	Two bottles of 70-count REBETOL 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs
Four PegIntron 150 mcg/0.5 mL Redipen Units	Two bottles of 84-count REBETOL 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs
Four PegIntron 150 mcg/0.5 mL Redipen Units	Two bottles of [redacted]-count REBETOL 200 mg Capsules	Each Redipen unit contains 1 B-D needle and 2 alcohol swabs

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[1,2] as well as several FDA databases[3,4] for existing drug names which sound-alike or look-alike to PegIntron/Rebetol Combo Pack to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[5]. The Saegis[6] Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies for the proposed name consisting of two written prescriptions and one verbal prescription order, involving health care practitioners within FDA. This exercise was conducted to simulate the ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, PegIntron/Rebetol Combo Pack. Potential concerns regarding drug marketing and promotion related to the proposed names were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC has no objections to the tradename "PegIntron/Rebetol Combo Pack" from a promotional perspective.

2. The Expert Panel identified 2 proprietary names that were thought to have the potential for look-alike or sound-alike confusion with PegIntron/Rebetol Combo Pack. These products are listed in Table 1 (pages 4-6), along with the dosage forms available and usual dosage.

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[1] MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[2] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.
[3] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-06, and the electronic online version of the FDA Orange Book.
[4] Phonetic and Orthographic Computer Analysis (POCA)
[5] WWW location http://www.uspto.gov/tmdb/index.html.
[6] Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at www.thomson-thomson.com

3. The Expert Panel noted that the proposed name, PEGIntron/Rebetol Combo Pack is very long and some computer systems and printers may find it difficult to fit the name in the existing data fields or on a prescription label. The name may be abbreviated to make it fit in these systems. DMETS is concerned that such abbreviations may pose a problem, however, DMETS is unable to ascertain what abbreviations may be used. Thus we are unable to evaluate the potential problems that abbreviations of this name might pose. (See Section C for further discussion.)

Table 1: PEGINTRON/REBETOL COMBO PACK: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel

Product Name	Dosage form(s); Established name	Usual adult dose	Other
PegIntron/ Rebetol Combo Pack	PegIntron/Peginterferon alfa-2b Powder for Injection: Vials: 50 mcg/vial, 80 mcg/vial, 120 mcg/vial and 150 mcg/vial Redipen: 50 mcg/unit, 80 mcg/unit, 120 mcg/unit and 150 mcg/unit Redipen 4-Pak: 4 - 50 mcg/unit, 80 mcg/unit, 120 mcg/unit and 150 mcg/unit (4 units per package)	Dose is individualized based on the patient's weight. Initially 1 mcg/kg/week for monotherapy or 1.5 mcg/kg/week in combination with ribavirin. If a serious adverse reaction develops during the course of treatment, discontinuation or modification of the PegIntron dosage by 50% may be necessary to 0.5 mcg/kg or 0.75 mcg/kg.	N/A
Combipatch	Transdermal Patch: Estradiol, 0.05 mg/24hr and Norethindrone Acetate, 0.14 mg/24hr Estradiol, 0.05 mg/24hr and Norethindrone Acetate, 0.25 mg/24hr	CombiPatch™ 9 cm^2 system (0.05 mg estradiol/ 0.14 mg norethindrone acetate per day) is worn continuously on the lower abdomen. The 16 cm^2 system (0.05 mg estradiol/0.25 mg norethindrone acetate per day) can be used if a greater progestin dose is desired. Replace CombiPatch™ twice weekly (every 3—4 days). Irregular bleeding may occur, especially within the first 6 months, but generally decreases with time. CombiPatch™ can be applied as a sequential regimen in combination with an estradiol-only transdermal delivery system. A 0.05 mg/day estradiol transdermal system is worn for the first 14 days, replacing the system twice weekly according to product directions. For the remaining 14 days of the 28-day cycle, CombiPatch™ 9 cm^2 system (0.05 mg estradiol/0.14 mg norethindrone acetate per day) is applied to the lower abdomen. The 16 cm^2 system (0.05 mg estradiol/0.25 mg norethindrone acetate per day) can be used if a greater progestin dose is desired. Replace Combipatch™ twice weekly (every 3—4 days).	LA/SA
Combipres	Chlorthalidone/Clonidine Hydrochloride Tablets: 15 mg/0.3 mg *Tradename and generics no longer marketed*	The dosage must be determined by individual titration with the separate components. Usual dose is 1 or 2 tablets orally two to four times daily. Further increments of 0.1 mg or 0.2 mg/day may be made until the desired response is achieved. Maximum recommended dosage is 2.4 mg of clonidine per day.	LA

*Frequently used, not all-inclusive
**LA (look-alike), SA (sound-alike)

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of PegIntron/Rebetol Combo Pack 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. These studies employed a total of 124 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the ordering process. Two prescription orders were written, each consisting of a combination of marketed and unapproved drug products and an order for PegIntron/Rebetol Combo Pack (see below). These orders were optically scanned and one order was delivered to a random sample of the participating health professionals via e-mail. In addition, a verbal order was recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: PegIntron/Rebetol Combo Pack #1 Take as directed	" PegIntron/Rebetol Combo Pack, dispense 1, take as directed"
Inpatient RX: PegIntron/Rebetol Combo Pack Take as directed	

2. Results for PegIntron/Rebetol Combo Pack:

None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. product. The majority of misinterpretations were misspelled/phonetic variations of the name, PegIntron/Rebetol Combo Pack. See Appendix A for the complete listing of interpretations from the verbal and written studies.

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name PegIntron/Rebetol Combo Pack, the primary concerns relating to look-alike and sound-alike confusion with PegIntron/Rebetol Combo Pack are the names Combipatch and Combipres, in addition to the currently marketed components of the co-packaged product, PegIntron and Rebetol. DMETS also noted that the name PegIntron/Rebetol Combo Pack is very long which may increase the potential for prescribers and computer systems/printers to use abbreviations for the name. In addition, DMETS noted that the practitioner may not be aware of the introduction of this Combo Pack and may dispense the separate product components or only one component.

DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that the proposed name could be confused with any of the aforementioned names. However, negative findings are not predictive as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to a small sample size. The majority of misinterpretations were misspelled/phonetic variations of PegIntron/Rebetol Combo Pack.

A. Sound-Alike/Look-Alike Names

Upon further review of the names identified as primary concerns, it was determined that Combipres is a brand name for a combination capsule of Chlorthalidone and Clonidine which is no longer marketed in brand or generic form, thus Combipres does not pose a safety risk. The name Combipatch was not reviewed further because it lacks convincing look-alike/sound-alike similarities with PegIntron/Rebetol Combo Pack, in addition to having numerous differentiating product characteristics such as the product strength, route of administration, indication for use, frequency of administration, and dosage form. Thus, this name does not pose a safety risk.

B. Problems with Length of Name

DMETS is concerned that the proposed name, PEGIntron/Rebetol Combo Pack, is very long and some prescribers and/or computer systems and printers may find it difficult to fit the name on a prescription, in the existing data fields or on a prescription label. The name may be abbreviated to make it fit in these systems. DMETS is concerned that such abbreviations may pose a problem, however, DMETS is unable to ascertain what abbreviations may be used. Thus we are unable to evaluate the potential problems that abbreviations of this name might pose. DMETS recommends that the Sponsor be made aware of the likelihood that abbreviations will be used, and they should take steps to reduce the potential for the name to be abbreviated.

C. New Packaging Configuration

DMETS is concerned that with the introduction of this new co-packaged product, there is potential for practitioners to dispense the separate component products when dispensing the prescription if they are not aware of the new co-packaged product, or it is not readily available in the pharmacy. The co-packaged product contains the same unit-of-use packages and strengths for the individual components of PegIntron Redipen and REBETOL Capsules. However, if the name PEGIntron/Rebetol Combo Pack is abbreviated, it is possible that the person dispensing the prescription might only dispense one of the components and not the other component. DMETS recommends that the Sponsor conduct a widespread marketing campaign to increase the healthcare professionals' awareness of this new co-packaged product.

In conclusion, DMETS has not identified any remaining names of concern with the potential for confusion with PegIntron/Rebetol Combo Pack and thus has no objections to the proposed name.

III. COMMENTS TO THE SPONSOR:

DMETS has not identified any remaining names of concern with the potential for confusion with PegIntron/Rebetol Combo Pack. However, in reviewing the proprietary name, DMETS is concerned

that the proposed name, PEGIntron/Rebetol Combo Pack, is very long and some prescribers and/or computer systems and printers may find it difficult to fit the name on a prescription, in the existing data fields or on a prescription label. The name may be abbreviated to make it fit in these systems. DMETS is concerned that such abbreviations may pose a problem, however, DMETS is unable to ascertain what abbreviations may be used. Thus we are unable to evaluate the potential problems that abbreviations of this name might pose. DMETS recommends that the Sponsor be made aware of the likelihood that abbreviations will be used, and they should take steps to reduce the potential for the name to be abbreviated.

BLA #
OSE Consult 2006-744

Appendix A: PegIntron/Rebetol Combo Pack

Outpatient	Voice	Inpatient
Peg Intron/Rebetol combo pack	Peg Intron/Rebetrol Combo Pack	Pegintron/Rebetol
Peg Intron/Rebetol Combo Pack	Pegatron/Robitron comb pack	Peglatrin/Rebetrol Combo Pack
Peg Intoron/Rebetol Combo Pack	Pegintron Revitrol Combopack	Peglatrin/Ribetol Combo Pack
PegInton/Rebetol combo pack	Pegintron-Rebital Combo Pack	PegIntron/Rebetol Combo Pack
Peg Intron/rebetol combo pack	Peg Intron-Rebetol Combo Pack	Peglutrin/Rebetol Combo Pack
Peg Intron/Rebetrol Combo Pack	Pegatron Robritrol Combo Pak	Peglatrin/Rebetol Combo Pack
PEG Intron/Rebetrol Combo Pack	Pegintron revitrol Combo Pack	PegIntron/Ribetol Combo Pack
Pegelutron/Rebetol Combo Pack	PegIntrol Rebatron combo pack	Pegintron/Rebetol Combo Pack
PegIntron/Rebetol combo pack		Peglatron/Rebetol
Peg Intron/Rebetol Combo Pack		PegIntron/Rebetol Combo Pack
Peg Intron/Rebetol Combo Pack		Peglatron/Rebetol
Peg Intron/Rebetol Combo Pack		PegIntron/Rebetol Combo Pack
Pegclutron/Rebetol Combo Pack		PegIntron/Rebetol Combo Pack
PegIntron/Rebetol combo pack		PegIntron/Rebetol