CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125544Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*****This document contains proprietary information that cannot be released to the public*****

Date of This Review:	November 19, 2015
Application Type and Number:	BLA 125544
Product Name and Strength:	Inflectra (CT-P13*) For Injection 100 mg per vial
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Celltrion
Panorama #:	2015-1649964
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Deputy Director:	Lubna Merchant, MS, PharmD

* Inflectra has been developed as a proposed biosimilar to US-licensed Remicade (infliximab). Since the proper name for Inflectra has not yet been determined, CT-P13 is used throughout this review as the proper name for this product.

Reference ID: 3849042

1 INTRODUCTION

The proposed proprietary name, Inflectra, was reviewed by DMEPA on February 23, 2015[1] and was found acceptable. However, BLA 125544 received a complete response on June 8, 2015. Celltrion resubmitted a response to the complete response along with a request to re-review the proposed proprietary name, Inflectra on October 5, 2015. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Inflectra, is acceptable from both a misbranding and safety perspective under the BLA 125544. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA searched the USAN stems list to determine if the name contains any USAN stems as of the last USAN updates. Our November 10, 2015 search of the USAN stems did not identify any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your, October 5, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[1] McMillan T. Proposed Proprietary Name Review for Inflectra (BLA 125544). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 FEB 23. Panorama No. 2014-44603.

Reference ID: 3849042

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TERESA S MCMILLAN
11/19/2015

KENDRA C WORTHY
11/20/2015

LUBNA A MERCHANT
11/20/2015

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
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Date of This Review:	February 23, 2015
Application Type and Number:	BLA 125544
Product Name and Strength:	Inflectra ("CT-P13"*) Injection 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Celltrion
Panorama #:	2014-44603
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

* Inflectra has been developed as a proposed biosimilar to US-licensed Remicade (infliximab). Since the proper name for Inflectra has not yet been determined, "CT-P13" is used throughout this review as the nonproprietary name for this product.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Inflectra, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant (Celltrion Inc.) submitted an external name study, conducted by (b) (4), for this product.

1.1 REGULATORY HISTORY

The applicant previously submitted the proposed proprietary name, (b) (4) on May 20, 2014 and September 26, 2014. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4) acceptable in OSE Review #2014-17373 and 2014-36963, dated October 28, 2014.

On November, 27, 2014, the applicant submitted the name, Inflectra, for review. The cover letter of the proposed proprietary name states that the proprietary name Inflectra, if approved, will be the primary marketed name, and (b) (4) (b) (4) . However, the applicant stated that they do not intend to market this product under the name (b) (4) and they would like to market the product exclusively as Inflectra in the United States.

On February 9, 2015, DMEPA asked the applicant to clarify their marketing intentions, advising Celltrion to withdraw the name (b) (4) if Celltrion intends to use only the name Inflectra in the US. FDA also provided clarification on the steps that would need to be taken if the Applicant was to pursue the use of the (b) (4) name pre- and post-approval, and clarified that FDA's conditional acceptance of any proposed proprietary name does not mean that FDA (b) (4) . On February 10, 2015, the applicant withdrew the proprietary name (b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the November 27, 2014 proprietary name submission.

- Intended Pronunciation: In flec tra
- Active Ingredient: "CT-P13" [1]* [proposed biosimilar to US-licensed Remicade (infliximab)]
- Indication of Use: Treatment of Crohn's Disease, Rheumatoid Arthritis, Pediatric Crohn's Disease, Ulcerative Colitis, (b) (4) Ankylosing Spondylitis, Psoriatic Arthritis, and Plaque Psoriasis
- Route of Administration: Intravenous

[1]*Inflectra has been developed as a proposed biosimilar to US-licensed Remicade (infliximab). Since the proper name for Inflectra has not yet been determined, "CT-P13" is used throughout this review as the nonproprietary name for this product.

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- Dosage Form: Injection
- Strength: 100 mg after reconstitution 10 mg/mL
- Dose and Frequency:

  Crohn's Disease

  - 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response.

  Pediatric Crohn's Disease, Ulcerative Colitis, (b) (4) (b) (4) Psoriatic Arthritis and Plaque Psoriasis

  - 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

  Rheumatoid Arthritis

  - In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
- How Supplied: Each 20 mL vial is individually packaged in a carton. An accumulator carton contains 10 vials.
- Storage: Refrigerated at 2˚C to 8˚C

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name does not misbrand the proposed product. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[2].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Inflectra in their submission. This proprietary name is comprised of a single word that

[2]USAN stem search conducted on January 5, 2015.

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does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Ninety-four practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline in the United States. However, one participant did identify the name Selectra, which is an international drug name for sertraline in Turkey. This name was further evaluated in Appendix G. Sixty-five participants interpreted the name correctly as "Inflectra". The remaining participants provided incorrect responses. The remaining misinterpretations from all responses occurred with the letter 'I' being misinterpreted for the letters 'D', 'E', 'O', 'P', 'S', and 'T', the letter 'n' for the letters 'i', 'r', 'e' and the letter string 'in', the letter 'f' for the letter string 'sy' or it was omitted, 'the letter 'c' for the letter 'x' or it was omitted, and the letter 'r' for the letter 'i'. Appendix B contains the results from the verbal and written prescription studies.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 11, 2014 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) forwarded a comment stating that the name Inflectra is also the name of a software development company. However, DMEPA determined this will not affect the safety of this proposed name.

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[3] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the (b) (4) external study.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	80
Low similarity name pair: combined match percentage score ≤49%	10

[3] POCA search conducted on 9/26/2014 and 1/5/2015.

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2.2.5 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 92 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on January 28, 2015. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on January 30, 2015, they stated no additional concerns with the proposed proprietary name, Inflectra.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Sarah Harris, OSE project manager, at 240-402-4774.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your November 27, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

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

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

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.

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APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. 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. [4]

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

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***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   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 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 record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for 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 OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/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 provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

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Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

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	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Inflectra Study (Conducted on 8/27/14)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Inflectra (b) (4) intravenous infusion today	Inflectra Bring to clinic #4
Outpatient Prescription: Inflectra Bring to clinic #4	

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FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

260 People Received Study

94 People Responded

Study Name: Inflectra

Total	**34**	**33**	**27**	**-**
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
DIFLECTRA	0	0	1	1
DINFLECTRA	0	0	2	2
ENFLECTRA	0	6	0	6
ENFLEXTRA	0	1	0	1
INFLECTIA	6	0	0	6
INFLECTRA	27	22	16	65
INFLETRA	0	1	0	1
INFLEXTRA	0	1	0	1
INSYLECTRA	0	1	0	1
ONFLECTRA	0	0	1	1
PIFLECTRA	0	0	2	2
PINFLECTIA	0	0	1	1
PINFLECTRA	0	0	3	3
PRIFLECTRA	0	0	1	1
SELECTRA	0	1	0	1
TRFLECTRA	1	0	0	1

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Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Inflectra **Strength(s):** 100 mg (after reconstitution 10 mg/mL) **Usual Dose:** • 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. • 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Max: 10 mg/kg	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion**
1.	Inflectra	100	Name is subject of review.
2.	Flextra	70	The prefix of the name pair has sufficient orthographic differences. This name contains one less syllable.

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Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Inflectra **Strength(s):** 100 mg (after reconstitution 10 mg/mL) **Usual Dose:** • 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. • 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Max: 10 mg/kg	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Flector	62	The prefix of this name pair has sufficient orthographic differences This name contains one less syllable.
2.	Endosol Extra	60	The infix and suffix of this name pair has sufficient orthographic differences. This name has two extra syllables.
3.	Menactra	60	The prefix and infix of this name pair has sufficient orthographic differences. The first and second syllables of this name pair sound different.
4.	Euflexxa	58	The suffix of this name pair has sufficient orthographic differences. The first and third syllables of this name pair sound different.
5.	Infliximab***	57	The suffix of this name pair has sufficient orthographic differences. This name has two extra syllables.
6.	Integra F	56	The infix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different.

7.	Inspra	55	The infix and suffix of this name pair has sufficient orthographic differences. This name has one less syllable.
8.	(b) (4) ***	55	The infix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different.
9.	Ixempra***	54	The infix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different.
10.	Ex-lax Ultra	53	The infix and suffix of this name pair has sufficient orthographic differences. This name has one extra syllable.
11.	Inlyta	53	The infix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different.
12.	Expecta	53	The infix of this name pair has sufficient orthographic differences. The first and second syllables of this name pair sounds different.
13.	INTELENCE	52	The infix and suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sounds different.
14.	Iodoflex	52	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. This name has one extra syllable.
15.	(b) (4) ***	52	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sounds different.
16.	Sectral	52	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. This name has one less syllable.

17.	Arixtra	52	The infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sounds different.
18.	Alustra	51	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sounds different.
19.	Hizentra	51	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sounds different.
20.	Injectafer	51	The infix and suffix of this name pair have sufficient orthographic differences. This name has one extra syllable.
21.	Soolantra***	50	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sounds different.
22.	Kaletra	50	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sounds different.
23.	Levitra	50	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sounds different.

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Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Anakinra	48
2.	Imitrex	47
3.	Celexa	46
4.	Inderal	46
5.	Infergen	45
6.	Imferon	42
7.	Interferon	42
8.	Infed	42
9.	Flecanide	41
10.	Atripla	37

Reference ID: 3706046

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	Inflaclor	68	Name was submitted in the external study and not found in the commonly used databases.
2.	Selectra	68	Name was submitted in the external study. This is an international name for the drug sertraline in Turkey.
3.	(b) (4) ***	65	Name not found in the commonly used databases.
4.	Ex-dec- TR	60	Name not found in the commonly used databases.
5.	Infestat	58	Name not found in the commonly used databases.
6.	Indoflex	57	Name not found in the commonly used databases.
7.	(b) (4) ***	56	IND (b) (4) was found conditionally acceptable in OSE Review # (b) (4) but application has been inactive since (b) (4).
8.	(b) (4) ***	56	Name withdrawn by applicant and approved as Staxyn, NDA 200179 on 6/17/10.
9.	Infalyte	54	Name not found in the commonly used databases.
10.	Emflex	54	Name not found in the commonly used databases.
11.	(b) (4) ***	52	NDA 201803 found unacceptable by OPDP Product approved with the name Advil on 6/12/12.

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12.	(b) (4)***	52	Name found unacceptable in name OSE Review 2013-16332. ANDA 203038 received a complete response on 5/27/14.
13.	Infectiguard	52	Name not found in the commonly used databases.
14.	Mint extract	52	Name not found in the commonly used databases.
15.	Pri-Dextra	52	Name not found in the commonly used databases.
16.	Iron dextran	51	NDA 010787 was withdrawn federal register effective on 06/16/2006. No therapeutic equivalents are available.
17.	Visine Extra	51	Name not found in the commonly used databases.
18.	(b) (4)***	51	Name was found conditionally acceptable in OSE Review # (b) (4). IND (b) (4) is still active.
19.	(b) (4)***	50	ANDA (b) (4) was withdrawn by the applicant on (b) (4). No other name has been submitted to the Agency for review.
20.	(b) (4)***	50	Secondary name for NDA 203100. Product approved with the name Stribild on 8/27/12.
21.	Indolar SR	50	Name not found in the commonly used databases.
22.	Injectapap	50	NDA 017785 withdrawn federal register effective on 7/7/1987. No therapeutic equivalents are available.
23.	Interceptor	50	Name not found in the commonly used databases.

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24.	Fectrim	50	Name not found in the commonly used databases.

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Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Entex LA	60
2.	Andec-TR	59
3.	ENFLURANE	56
4.	Synflex	55
5.	Ed Flex	54
6.	Rondec-TR	54
7.	Enfolast-N	54
8.	Banflex	53
9.	Bioflexor	52
10.	Entex ER	52
11.	FLEXERIL	52
12.	Nalex-A	52
13.	Nalex-A 12	52
14.	NORLESTRIN 21 1/50	52
15.	NORLESTRIN 21 2.5/50	52
16.	NORLESTRIN 28 1/50	52
17.	Phenflu CD	52
18.	Elestrin	52
19.	Cidaflex	51
20.	(b) (4) ***	51
21.	Entresto ***	51
22.	Exgest LA	51
23.	(b) (4) ***	51
24.	Amitex LA	50
25.	Ami-Tex LA	50
26.	Anaflex	50
27.	ENABLEX	50
28.	ENTECAVIR	50

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29.	Lantex-LA	50
30.	Phentex LA	50
31.	Santex LA	50
32.	(b) (4) ***	50
33.	Unna-Flex	50

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/s/

TERESA S MCMILLAN
02/23/2015

KENDRA C WORTHY
02/23/2015

LUBNA A MERCHANT
02/23/2015

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	October 28, 2014
Application Type and Number:	IND 118135 BLA 125544
Product Name and Strength:	(b) (4) ("CT-P13"*) Injection 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Celltrion
Submission Date:	May 20, 2014 and September 26, 2014
Panorama #:	2014-17373 and 2014-36963
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

* (b) (4) has been developed as a proposed biosimilar to Remicade® (infliximab). Since the proper name fo (b) (4) has not yet been determined, "CT-P13" is used throughout this review as the nonproprietary name for this product.

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/s/

TERESA S MCMILLAN
10/28/2014

KENDRA C WORTHY
10/28/2014

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10/28/2014