CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-107

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; White Oak 22, Mail Stop 4447)

DATE RECEIVED: May 22, 2007 **DATE OF DOCUMENTS:** March 17, 2007	**DESIRED COMPLETION DATE:** November 1, 2007 **PDUFA:** January 20, 2008	**OSE REVIEW #:** 2007-1029

TO: Norman Stockbridge, M.D.
Director, Division of Cardiovascular and Renal Products
HFD-110

THROUGH: Linda Kim-Jung, Pharm.D., Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, R.Ph., Director
Division of Medication Errors and Technical Support

FROM: Walter Fava, R.Ph. Safety Evaluator
Division of Medication Errors and Technical Support

PRODUCT NAME: **Tekturna HCT**
(Aliskiren/Hydrochlorothiazide Tablets)
150 mg/12.5 mg; 150 mg/25 mg; 300 mg/12.5 mg; 300 mg/25 mg

NDA#: 22-107

NDA SPONSOR: Novartis Pharmaceuticals Corporation

RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary name, Tekturna HCT.

2. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review to minimize potential errors with the use of this product.

3. DDMAC finds the proprietary name Tekturna HCT, acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. Please copy DMETS on any correspondence forwarded to the sponsor concerning this review. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Darrell Jenkins, Project Manager, at 301-796-0558.

Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
HFD-420; White Oak 22, Mail Stop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME, LABEL, AND LABELING REVIEW

DATE OF REVIEW: September 26, 2007

NDA#: 22-107

NAME OF DRUG: Tekturna HCT
(Aliskiren/Hydrochlorothiazide Tablets)
150 mg/12.5 mg; 150 mg/25 mg; 300 mg/12.5 mg; 300 mg/25 mg

NDA HOLDER: Novartis Pharmaceuticals Corporation

I. INTRODUCTION:

This consult was written in response to a request from the Division of Cardiovascular and Renal Products (HFD-110), for assessment of the proprietary name, Tekturna HCT, regarding potential name confusion with other proprietary or established drug names. Container labels, carton, and insert labeling were provided for review and comment.

Upon initial analysis of the name, DMETS identified failure modes with the use of this name and product labeling. We had a meeting to discuss these issues and this review outlines the problems discussed with the Division on November 27, 2007 and subsequently again on December 5, 2007.

PRODUCT INFORMATION

Tekturna HCT (Aliskiren/Hydrochlorothiazide Tablets) is a combination drug product containing non-peptide renin inhibitor and a diuretic. It is proposed for the treatment of hypertension as monotherapy or in combination with other anti-hypertensive agents. The sponsor has proposed a 150 mg/ 12.5 mg; 150 mg/25 mg; 300 mg/12.5 mg; and 300 mg/25 mg strength. All strengths will be packaged in bottles of 30 or 90 tablets and in unit dose blister packages of 100 tablets (10 strips of 10 tablets per strip).

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 Tekturna HCT 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

[1] MICROMEDEX Integrated Index, 2007, 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 98-07, and the electronic online version of the FDA Orange Book.
[4] Phonetic and Orthographic Computer Analysis (POCA)

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, for each name DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription 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, Tekturna HCT. Potential concerns regarding drug marketing and promotion related to the proposed name 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, Tekturna HCT, from a promotional perspective.

2. The Expert Panel identified three proprietary names that were thought to have the potential for confusion with Tekturna HCT. These names are Tekturna, Teveten HCT, and Trandate HCT.

Additionally, members of the Expert Panel identified concerns with the modifier "HCT". Discussion included the fact that "HCT" is included on ISMP's list of error-prone abbreviations and one participant submitted a list of possible interpretations of the modifier "HCT" which include: Health Check Test, Heart-circulation Training, Hematocrit, Histamine Challenge Test, Historic Control Trial, Homocytotropic, Human Calcitonin, Human Chorionic Thyrotropin, Hydrochlorothiazide, Hydroxycortisone, and Hydrocortisone. Another EPD panelist noted that the IOM report cited dangerous abbreviations as an important issue in medication errors, and the JCAHO's National Patient Safety Guidelines require organizations to avoid using dangerous abbreviations. The same panelist mentioned that in June 2006, the FDA launched a campaign with ISMP to educate health care providers about the use of dangerous abbreviations.

B. ADVERSE EVENT REPORTING SYSTEM

A search was conducted of the AERS database for Tekturna in an effort to evaluate existing medication errors which may pertain to potential issues regarding Tekturna HCT. The search criteria used included the active ingredient "aliskeren", tradename "Tekturna", and the verbatim terms "alisk%" and "Tek%". No cases of medication errors were identified from the search. Additional searches were also conducted using alternate name presentations of currently approved proprietary names of antihypertensive products which include hydrochlorothiazide, (i.e., TRADEMARKretic and TRADEMARKzide). This was done to assess the risk of medication errors for all proprietary names which incorporate the antihypertensive component and the hydrochlorothiazide component into a single name vs names with the antihypertensive component plus the modifier HCT. Although no medication errors were identified involving

[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

misinterpretation of the modifier HCT, medication errors for both proprietary name presentations involving name confusion due to look-alike and sound-alike issues were identified.

C. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Tekturna HCT 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. Each name study employed a total of 124 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Tekturna HCT (see pages 5-6). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were 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 prescription orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

Tekturna HCT

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: Tekturna HCT 150/12.5 #30 1 tab po daily	"Tekturna HCT 150/12.5 mg #30 Take one tablet by mouth daily"
Inpatient RX: Tekturna HCT 150/12.5mg tablet po qd	

a. Results for Tekturna HCT:

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 proposed name, Tekturna HCT. See Appendix A (page 10) for the complete listing of interpretations from the verbal and written studies.

D. SAFETY EVALUATOR RISK ASSESSMENT

To evaluate the potential of medication errors with the proposed name, Tekturna HCT, DMETS reviewed aspects that commonly lead to errors when new drugs and/or in this case a product extension is introduced in the marketplace. These include but are not limited to the following: modifier omissions, possible misinterpretation of the modifier, orthographic and phonetic similarity of the name, and appropriateness of the modifier.

1. Potential for Product Line Confusion

Tekturna (Aliskeren) is currently available in the marketplace as 150 mg and 300 mg tablets. Tekturna HCT will be the first extension of the Tekturna product line. Errors introduced by product line extensions are well known occurrences at all points in the medication use process (i.e., prescribing, computer selection, dispensing, administering, and monitoring). These errors are multi-factorial in nature, which can stem from the timing of the product launch, similar product names, overlapping product characteristics coupled with the low level of awareness or knowledge of the new product profile by healthcare professionals and patients.

a. Overlapping Product Characteristics

Both Tekturna and Tekturna HCT share overlapping product characteristics such as indication of use, dosage forms, strengths, and dosing frequency, which increase the risk for confusion and medication errors. Tekturna is available as a 150 mg and 300 mg tablet administered by mouth once a day. Tekturna HCT will be available as 150 mg/12.5 mg, 150 mg/25 mg, 300 mg/12.5 mg, and 300 mg/25 mg tablets administered by mouth once a day. All the aforementioned product characteristics could be a source of confusion especially when coupled with the fact that healthcare professionals may not be fully aware of the new product or the differences between the two drugs. This is supported by postmarketing error reports documenting confusion for other currently marketed products and similar products such as Diovan and Diovan HCT. These products were confused for one another when the new product was introduced onto the market.

b. Prescribing Errors

Prescribing errors can occur when a new product line extension is introduced into the market. A common cause of these errors is when prescribers omit the modifier[7]. In most cases name modifiers indicate a different dosage formulation of an existing of an existing product (i.e., delayed or extended-release). In this case, "HCT" represents an additional ingredient rather than a modification to an existing product. Thus, if the prescriber omits the "HCT" portion of the name Tekturna will likely be dispensed. This may result in inappropriate treatment and poor control of the patient's hypertension. This may occur despite the fact that the strength of Tekturna HCT differs from Tekturna. However, the inclusion of the strength may serve as a prompt to the pharmacist/nurse to obtain clarification of the order.

[7] Lesar TS, Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

Based on postmarketing reports of medication errors resulting from confusion between products containing the HCT modifier, and differences in strength DMETS anticipates similar confusion between Tekturna and Tekturna HCT once Tekturna HCT is approved and marketed.

c. Shelf and Computer Selection Errors

Tekturna and Tekturna HCT will likely be stored in close proximity to one another on a pharmacy or distributor/warehouse shelf. Typically, pharmaceutical products are organized alphabetically by proprietary name, established name, or sorted by manufacturer. Since these attributes are similar with Tekturna and Tekturna HCT products, it is likely that these products will be stored near one another in virtually any organization carrying both products. There is also a strong likelihood of label similarity between the products since they are from the same manufacturer. Thus, close storage proximity and similarity in label appearance may increase the risk of product selection errors. In order to minimize this potential source of confusion, differentiation in the packaging and labeling of Tekturna and Tekturna HCT is essential.

Another concern, due to the shared root name of "Tekturna", is the possibility for computer selection errors, in which the wrong name will be selected from a computer list of names beginning with the same character string. Differentiation of labels and labeling will not be apparent during the computer entering process. Thus, education of practitioners will be extremely important so that they can make appropriate entries into their computer databases to differentiate these two names in their product menus to minimize computer selection errors.

In summary, DMETS anticipates medication errors within the Tekturna product line. Thus, it is imperative that the sponsor uses prudence in their educational campaign, and packaging and labeling of the combination product to minimize the potential for errors within the Tekturna product line.

2. Analysis of HCT

DMETS evaluated the appropriatness of the use of "HCT" in the name of this product. We considered how "HCT" might be interpreted. We also analyzed the potential for "HCT" to resemble any numbers, dosing instructions, or medical abbreviations, and considered comments concerning HCT from the DMETS Expert Panel in our analysis. DMETS Expert Panel Discussion noted that "HCT" could have multiple interpretations which were found using Medilexicom, a medical dictionary search engine, and the handbook Medical Abbreviations[8]. These interpretations included Head Computerized Tomography, Health Check Test, Heart-Circulation Training, Hematocrit, Histamine Challenge Test, Historic Control Trial, Homcytotropic, Human Chorionic Thyrotropin, Human Calcitonin and "Hundred Count". However, we believe these interpretations should not result in either product or dosing confusion due to different context of use.

Furthermore, the Expert Panel also noted "HCT" appears on the "ISMP List of Error Prone Abbreviations, Symbols, and Dose Designations" because it has been confused to mean hydrocortisone. In addition to the possibility of confusion with hydrocortisone, they also discussed the fact that LexiComp lists "HCT" as a medical abbreviation for hydroxycortisone. DMETS notes that hydroxycortisone is not a marketed finished dosage form drug product, and therefore poses minimal risk and will not be discussed further in this

review. It is however, plausible that a healthcare provider who is unfamiliar with this abbreviation, may use the Medical Abbreviations handbook as a reference to determine what "HCT" means, and end up dispensing Tekturna and Hydrocortisone. The product strengths of Tekturna HCT may however diminish the potential for the risk of the modifier to be misinterpreted as hydrocortisone because there is no numerical overlap between the strengths of hydrocortisone (5 mg, 10 mg and 20 mg) and the hydrochlorothiazide component of Tekturna HCT (12.5 mg and 25 mg).

DMETS acknowledges that there are currently six FDA approved products containing hydrochlorothiazide with the abbreviation "HCT" in the proprietary name (Lotensin HCT, Atacand HCT, Teveten HCT, Diovan HCT, Trandate HCT, and Benicar HCT). However, these proprietary names were approved prior to the June 14, 2006, FDA's launch of a nationwide health professional education campaign aimed at reducing the number of common but preventable sources of medication errors caused by the use of unclear medical abbreviations. This campaign warned against using abbreviations that appear on the aforementioned dangerous abbreviations list.

We noted in our analysis that there are two presentations of combination antihypertensive products containing hydrochlorothiazide that are currenly approved. The first uses the modifier "HCT" with the root name (i.e., Lotensin HCT, Atacand HCT, Teveten HCT, Diovan HCT, Trandate HCT, and Benicar HCT). The second presentation involves a proprietary name containing reference to the root name and hydrochlorothiazide into a single name. Some products use the ending of "zide" whereas others use "etic". The products include Vaseretic, Uniretic, Tenoretic, Zestoretic, Quinaretic, Accuretic, Capozide, Apresazide, Aldactazide, and Prinzide.

Since HCT is on the dangerous abbreviations list and used for a number of other marketed products, we further evaluated the naming convention of HCT against products that did not use "HCT" as part of their name but rather used a single name, We tried to assess if one method of naming these products was safer than the other method, if any.

Overall, based on searches of the AERS database using presentations for all of the aforementioned names, it appears both naming conventions have resulted in some confusion. Both have the risk of being confused with other names of different drug products. However, the "HCT" presentation offers an additional risk over the single name confusion. This risk is one of omission of the "HCT" from a prescription. Additionally, DMETS reiterates that use of this modifier is in direct conflict with the Agency's June 15, 2006 press release supporting the error prone medical abbreviations list published by the Institute of Safe Medication Practices (ISMP).

3. Look-alike and sound-alike name concerns

In reviewing the proprietary name for its similarity in appearance and phonetics to other currently marketed products, three names were identified as having the potential to look similar to Tekturna HCT: Tekturna, Teveten HCT, and Trandate HCT. 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 predicative 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 the proposed name, Tekturna HCT.

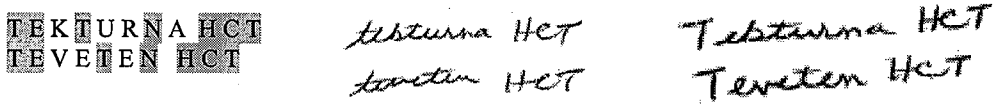
In evaluating this name, we believe the greatest potential for error will occur between Tekturna and Tekturna HCT because of overlapping product characteristics such as sharing the same root name "Tekturna", the same frequency of administration, and the numerical overlap in the Tekturna portion of the strengths (150 mg and 300 mg) (see section II C 1). Of the remaining two names identified as having the potential for look-alike confusion with Tekturna HCT, Trandate HCT was not further evaluated because it is a discontinued product and is not available generically. Teveten HCT, is described in Table 1 and discussed below.

Table 1: Potential Sound-Alike/Look-Alike Names Identified for Tekturna HCT

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Tekturna HCT	Aliskiren/Hydrochlorothiazide Tablets: 150 mg/12.5 mg, 150 mg/25 mg 300 mg/12.5 mg, 300 mg/25 mg	150 mg orally once daily for starting dose. Maximum dose is 300 mg daily.	N/A
Tekturna	Aliskiren Tablets: 150 mg, 300 mg	150 mg orally once daily for starting dose. Maximum dose is 300 mg daily.	SA/LA
Teveten HCT	Eprosartan mesylate; hydrochlorothiazide Tablets: 600 mg/12.5 mg; 600 mg/25 mg	Starting dose is 600 mg/12.5 mg orally once a day up to a maximum of 900 mg/day of oral eprosartan and 25 mg/day of oral hydrochlorothiazide.	LA
*Frequently used, not all-inclusive. **LA (look-alike), SA (sound-alike)			

Teveten HCT is an antihypertensive medication containing the angiotensin II converting enzyme inhibitor eprosartan mesylate and the diuretic, hydrochlorothiazide.

Look-alike similarities between the Tekturna HCT and Teveten HCT include the fact that they both begin with the same two letters "TE" and both have the same modifier, "HCT". The name pair also share an upstroke characteristic with the letter "t" and the letter "n" in similar positions and sequence of the names.



Tekturna HCT, however, does have an extra upstroke with the letter "k", but this difference may not be readily noticeable due to the prominent look-alike similarities with the beginning and ending of the names.

Additionally, these two products have overlapping product characteristics, such as indication of use (anti-hypertensive with a diuretic), dosage form (tablet), and frequency of administration (once a day). Tekturna HCT will be available in 150 mg/12.5 mg, 150 mg/25 mg, 300 mg/12.5 mg, 300 mg/25 mg strengths which does not share overlapping numerical strengths with Teveten HCT, which is available as 600 mg/12.5 mg and 600 mg/25 mg tablets. However, DMETS notes that the higher strength of Teveten HCT (600 mg/25 mg) is attainable if the name is confused and a health care professional dispenses two tablets of Tekturna HCT 300 mg/12.5 mg. Conversely, the 300 mg/12.5 mg dose of Tekturna HCT can be achieved by cutting a Teveten HCT 600 mg/25 mg tablet in half.

DMETS also considered the fact that Teveten HCT has been on the market since November 2001 and thus has gained name recognition by healthcare providers. Name recognition and familiarity with Teveten HCT coupled with unfamiliarity with Tekturna HCT upon its launch into the marketplace increases the likelihood that scripted orders for Tekturna HCT could be misinterpreted and as Teveten HCT.

Thus, DMETS does not believe Tekturna HCT and Teveten HCT can safely co-exist in the marketplace.

III. COMMENTS TO THE SPONSOR:

DMETS does not recommend the use of the name Tekturna HCT because of safety concerns related to the "HCT" portion of the name. Additionally, DMETS identified look-alike and sound-alike name concerns between Tekturna HCT and Tekturna, as well as between Tekturna HCT and Teveten HCT. These concerns have been explained in detailed in this review and are reiterated below.

1. Potential for Product Line Confusion

Tekturna (Aliskeren) is currently available in the marketplace as 150 mg and 300 mg tablets. Tekturna HCT will be the first extension of the Tekturna product line. Errors introduced by product line extensions are well known occurrences at all points in the medication use process (i.e., prescribing, computer selection, dispensing, administering, and monitoring). These errors are multi-factorial in nature, which can stem from the timing of the product launch, similar product names, overlapping product characteristics coupled with the low level of awareness or knowledge of the new product profile by healthcare professionals and patients.

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Prescribing errors can occur when a new product line extension is introduced into the market. A common cause of these errors is when prescribers omit the modifier[8]. In most cases name modifiers indicate a different dosage formulation of an existing of an existing product (i.e., delayed or extended-release). In this case, "HCT" represents an additional ingredient rather than a modification to an existing product. Thus, if the prescriber omits the "HCT" portion of the name Tekturna will likely be dispensed. This may result in inappropriate treatment and poor

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control of the patient's hypertension. This may occur despite the fact that the strength of Tekturna HCT differs from Tekturna. However, the inclusion of the strength may serve as a prompt to the pharmacist/nurse to obtain clarification of the order.

Based on postmarketing reports of medication errors resulting from confusion between products containing the HCT modifier, and differences in strength DMETS anticipates similar confusion between Tekturna and Tekturna HCT once Tekturna HCT is approved and marketed.

c. Shelf and Computer Selection Errors

Tekturna and Tekturna HCT will likely be stored in close proximity to one another on a pharmacy or distributor/warehouse shelf. Typically, pharmaceutical products are organized alphabetically by proprietary name, established name, or sorted by manufacturer. Since these attributes are similar with Tekturna and Tekturna HCT products, it is likely that these products will be stored near one another in virtually any organization carrying both products. There is also a strong likelihood of label similarity between the products since they are from the same manufacturer. Thus, close storage proximity and similarity in label appearance may increase the risk of product selection errors. In order to minimize this potential source of confusion, differentiation in the packaging and labeling of Tekturna and Tekturna HCT is essential.

Another concern, due to the shared root name of "Tekturna", is the possibility for computer selection errors, in which the wrong name will be selected from a computer list of names beginning with the same character string. Differentiation of labels and labeling will not be apparent during the computer entering process. Thus, education of practitioners will be extremely important so that they can make appropriate entries into their computer databases to differentiate these two names in their product menus to minimize computer selection errors.

In summary, DMETS anticipates medication errors within the Tekturna product line. Thus, it is imperative that the sponsor uses prudence in their educational campaign, and packaging and labeling of the combination product to minimize the potential for errors within the Tekturna product line.

2. Analysis of HCT

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DMETS acknowledges that there are currently six FDA approved products containing hydrochlorothiazide with the abbreviation "HCT" in the proprietary name (Lotensin HCT, Atacand HCT, Teveten HCT, Diovan HCT, Trandate HCT, and Benicar HCT). However, these proprietary names were approved prior to the June 14, 2006, FDA's launch of a nationwide health professional education campaign aimed at reducing the number of common but preventable sources of medication errors caused by the use of unclear medical abbreviations. This campaign warned against using abbreviations that appear on the aforementioned dangerous abbreviations list.

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Since HCT is on the dangerous abbreviations list and used for a number of other marketed products, we further evaluated the naming convention of HCT against products that did not use "HCT" as part of their name but rather used a single name, We tried to assess if one method of naming these products was safer than the other method, if any.

Overall, based on searches of the AERS database using presentations for all of the aforementioned names, it appears both naming conventions have resulted in some confusion. Both have the risk of being confused with other names of different drug products. However, the "HCT" presentation offers an additional risk over the single name confusion. This risk is one of omission of the "HCT" from a prescription. Additionally, DMETS reiterates that use of this modifier is in direct conflict with the Agency's June 15, 2006 press release supporting the error prone medical abbreviations list published by the Institute of Safe Medication Practices (ISMP).

3. Look-alike and sound-alike name concerns

Teveten HCT is an antihypertensive medication containing the angiotensin II converting enzyme inhibitor eprosartan mesylate and the diuretic, hydrochlorothiazide.

Look-alike similarities between the Tekturna HCT and Teveten HCT include the fact that they both begin with the same two letters "TE" and both have the same modifier, "HCT". The name pair also share an upstroke characteristic with the letter "t" and the letter "n" in similar positions and sequence of the names.

tekturna HCT
teveten HCT

Tekturna HCT
Teveten HCT

Tekturna HCT, however, does have an extra upstroke with the letter "k", but this difference may not be readily noticeable due to the prominent look-alike similarities with the beginning and ending of the names.

Additionally, these two products have overlapping product characteristics, such as indication of use (anti-hypertensive with a diuretic), dosage form (tablet), and frequency of administration (once a day). Tekturna HCT will be available in 150 mg/12.5 mg, 150 mg/25 mg, 300 mg/12.5 mg, 300 mg/25 mg strengths which does not share overlapping numerical strengths with Teveten HCT, which is available as 600 mg/12.5 mg and 600 mg/25 mg tablets. However, DMETS notes that the higher strength of Teveten HCT (600 mg/25 mg) is attainable if the name is confused and a health care professional dispenses two tablets of Tekturna HCT 300 mg/12.5 mg. Conversely, the 300 mg/12.5 mg dose of Tekturna HCT can be achieved by cutting a Teveten HCT 600 mg/25 mg tablet in half.

DMETS also considered the fact that Teveten HCT has been on the market since November 2001 and thus has gained name recognition by healthcare providers. Name recognition and familiarity with Teveten HCT coupled with unfamiliarity with Tekturna HCT upon its launch into the marketplace increases the likelihood that scripted orders for Tekturna HCT could be misinterpreted and as Teveten HCT.

Thus, DMETS does not believe Tekturna HCT and Teveten HCT can safely co-exist in the marketplace.

IV. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

DMETS notes that in our meeting with the Division on November 27, 2007, we had forwarded our preliminary labeling comments to the review Division. Subsequently, on Decemeber 11, 2007, the sponsor submitted a revised container label and carton labeling addressing our label/labeling recommendations. DMETS acknowledges that the sponsor implemented all of the recommended container label and carton labeling changes in their December 11, 2007 submission. DMETS has no further recommendations for the carton labels and container labeling at this time. However, no revised package insert labeling was submitted for review and therefore, we'll reiterate our package insert labeling recommendation below.

A. PACKAGE INSERT LABELING

b(4)

b(4)

Appendix A.

Rx Study Results for Tekturna HCT

Outpatient	Inpatient	Voice
Tekturna/HCT	Teletinna HCT	Techtourna HCT 150/12.5 mg
Tekturna HCT 150/12.5	Teletunna HCT 150/12.5 mg	Techturna HCT 150/12.5 mg
Tekturna HCT 150/12.5	Teltirna HCT 150/12.5 mg	Teterna HCT 150/12.5 mg
Tekturna HCT 150/12.5	Teletunna HCT	Techturna HCT 150/12.5 mg
Tekturna HCT 150/12.5 mg	Tolotinna HCT 150/12.5 mg	Tekturna HCT 150/12.5 mg
Tekturna HCT 150/12.5	Teletrinna HCT	Tekturna HCT 150/12.5 mg
	Tektinna HCT	Techturna HCTZ
		Teturna HCT 150/12.5 mg
		Tecturna HCT 150/15.5 mg
		Tecturna HCT 150/12.5 mg

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✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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/s/

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