2005 DRAFTING REQUEST

Assembly Substitute Amendment (ASA-AB258)

Received: **08/15/2005**

Received By: **csundber**

Wanted: **As time permits**

Identical to LRB:

For: **Curtis Gielow (608) 266-0486**

By/Representing: **Dick Sweet**

This file may be shown to any legislator: **NO**

Drafter: **csundber**

May Contact:

Addl. Drafters:

Subject: **Occupational Reg. - prof lic**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Gielow@legis.state.wi.us**

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Nomenclature changes: generics and brand names

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	csundber 08/24/2005	wjackson 08/25/2005		_____ _____			
/1			pgreensl 08/26/2005	_____ _____	lnorthro 08/26/2005	lnorthro 08/26/2005	

FE Sent For:

<END>

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/?	csundber						

FE Sent For:

<END>

Sundberg, Christopher

From: Sweet, Richard
Sent: Friday, August 12, 2005 10:18 AM
To: Sundberg, Christopher
Cc: Sawyer, Julie
Subject: FW: AB 258 drafting notes 8-10-05
Attachments: AB 258 drafting notes 8-10-05.doc

Chris,

Julie Sawyer from Rep. Gielow's office asked that I forward this information to you and request a substitute amendment to AB 258. The substitute amendment would be along the lines of the suggestion about 2/3 of the way down on page 5 of the attached memo. It would refer to generics and brand names rather than drug product equivalents.

Thanks for your help.

Dick Sweet
Richard Sweet
Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
richard.sweet@legis.state.wi.us

From: Black, William
Sent: Wednesday, August 10, 2005 3:36 PM
To: Sweet, Richard; 'Marshland Pharmacies, Inc - Horicon'; Rowe, Sandra - DRL; Martin, Larry - DRL; Black, William
Subject: AB 258 drafting notes 8-10-05

Here are my drafting notes and suggestions attached.

Jim Doyle
Governor

Celia M. Jackson
Secretary

WISCONSIN DEPARTMENT OF REGULATION & LICENSING

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August 3, 2005

To: Richard Sweet

From: William A. Black,
Legal Counsel
Wisconsin Pharmacy Examining Board
608-266-1790

Re: Drafting note on AB 258 (LRB-0913/2)

1. Overview of Nomenclature

The nomenclature for drug products alternates between technical and regulatorily authorized terms such as "proprietary", "non proprietary", "established name" and "compendial name" versus the more commonly used terms, "generic" and "brand".

The context in which a certain type of nomenclature is used for a drug product will be based on the degree of technical usage required.

The FDA has an Office of Generic Drugs, although the term "generic" is a misnomer. This fact is acknowledged implicitly by the FDA in that a "generic" product manufacturer is a manufacturer producing a drug product with the same active ingredient as the "brand name" or "proprietary" name product:

> You can search for generic equivalents by using the "Electronic Orange Book" at http://www.fda.gov/cder/ob/default.htm and search by proprietary "brand" name," then search again by using the active ingredient name. **If other manufacturers are listed besides the "brand name" manufacturer when searching by the "active ingredient," they are the generic product manufacturers. [emphasis added]**
>
> Since there is a lag time after generic products are approved and they appear in the "Orange Book," you should also consult the most recent monthly approvals for "First Generics" at http://www.fda.gov/cder/ogd/approvals/default.htm.

21 CFR § 299 et seq., authorizes the FDA to adopt an "official" name. Section 299.4(a) references section 502(e) of the Federal Food, Drug, and Cosmetic Act, (as amended) and

requires a label to, "...bear its established name, if there is one, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)."

Section 502(e)(3) of the Act defines the "established" name to be:

1) an official name designated by the FDA, or

2) an official compendium name, or

3) if neither 1 nor 2 apply, the common or usual name.

The FDA by rule in 21 CFR § 299.4 (c) and (d), adopt the use of the non proprietary name for a drug selected by the U.S. Adopted Names Council (USAN). The USAN is sponsored in part by the United States Pharmacopeia. As a result, the FDA deems that typically no "official" name will be adopted, rather the "established" name will be the resulting compendial name. (21 CFR § 299.(4)(e))

To summarize, both the FDA and Orange Book do not "technically" use the term "generic" but rather, the "proprietary" name, is the same as a "brand" name; and a "non proprietary" name, will be the USP compendial name.(The established USAN name)

The actual focus for what a "generic" actually is for purposes of substitution, therefore, is not nomenclature, but rather therapeutic equivalence.

Example-

Orange book lists by "active ingredient" and "proprietary name"

Active Ingredient:	RANITIDINE HYDROCHLORIDE
Dosage Form;Route:	TABLET, EFFERVESCENT; ORAL
Proprietary Name:	ZANTAC 150
Applicant:	GLAXOSMITHKLINE
Strength:	EQ 150MG BASE
Application Number:	020251
Product Number:	001
Approval Date:	Mar 31, 1994
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	

The "active ingredient", ranitidine hybrochloride, is listed in 23 USP 1360 by its "non proprietary, established USON name". The brand name, ie..proprietary name, "Zantac", is not listed in the USP.

The Orange Book, therefore lists both the established name and the proprietary name. In more common parlance, these would be deemed the "generic" and "brand" names respectively.

The Orange Book is designed to demonstrate, in part, drug products that are "pharmaceutically equivalent" or "pharmaceutically alternative", from which the determination of "therapeutic equivalence may be made":

Pharmaceutical Equivalents. Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration (e.g., chlordiazepoxide hydrochloride, 5mg capsules). Pharmaceutically equivalent drug products are formulated to contain the same amount of active ingredient in the same dosage form and to meet the same or compendial or other applicable standards (i.e., strength, quality, purity, and identity), but they may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration time, and, within certain limits, labeling.

Pharmaceutical Alternatives. Drug products are considered pharmaceutical alternatives if they contain the same therapeutic moiety, but are different salts, esters, or complexes of that moiety, or are different dosage forms or strengths (e.g., tetracycline hydrochloride, 250mg capsules vs. tetracycline phosphate complex, 250mg capsules; quinidine sulfate, 200mg tablets vs. quinidine sulfate, 200mg capsules). Data are generally not available for FDA to make the determination of tablet to capsule bioequivalence. Different dosage forms and strengths within a product line by a single manufacturer are thus pharmaceutical alternatives, as are extended-release products when compared with immediate- or standard-release formulations of the same active ingredient.

If a drug product is deemed FIRST to be pharmaceutically equivalent, the NEXT step is to determine if it is a "therapeutic equivalent":

Therapeutic Equivalents. Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

The concept of therapeutic equivalence, as used to develop the List, applies only to drug products containing the same active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition (e.g., propoxyphene hydrochloride vs. pentazocine hydrochloride for the treatment of pain).

Therefore, the FDA will consider a drug product to be therapeutically equivalent if:

A. Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drug products for which:

(1) there are no known or suspected bioequivalence problems. These are designated AA, AN, AO, AP, or AT, depending on the dosage form; or

(2) actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence. These are designated **AB**.

B. Drug products that FDA at this time, considers NOT to be therapeutically equivalent to other pharmaceutically equivalent products, i.e., drug products for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence. Often the problem is with specific dosage forms

rather than with the active ingredients. These are designated BC, BD, BE, BN, BP, BR, BS, BT, BX, or B*.

2. Wisconsin regulation

For state law purposes, current Wis. Stat. § 450.13, the "generic substitution" section, accurately and correctly avoids the general terminology of "generic" versus "brand", rather the focus is correctly based upon "therapeutic equivalence" as determined by the FDA. (Wis. Stat. § 450.13(1))

Wis. Stat. Ch. 450 does contain a definition of "generic" and "brand" names for drug products:

450.12 Labeling of prescription drugs and prescription drug products.

(1) In this section:

(a) "Brand name" means the name, other than the generic name, that the labeler of a drug or drug product places on its commercial container at the time of packaging.

(b) "Generic name" means the official or established name given a drug by theU.S. department of health and human services or the U.S. adopted names council.

It is suggested that these definitions be moved to the definitions section of Chapter 450, so that they apply equally throughout Chapter 450 and to any labeling section where the substantive provisions of AB 258 may finally result.

I direct attention to the manner in which of Iowa has dealt with this issue of labeling as illustrative:

IOWA RULES

"Brand name" and "generic name" are defined first:

IC155A.3 Definitions

4. "*Brand name*" or "*trade name"* means the registered trademark name given to a drug product or ingredient by its manufacturer, labeler, or distributor.

19. "*Generic name"* means the official title of a drug or drug ingredient published in the current official United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia, or other drug compendium published by the United States pharmacopoeial convention or any supplement to any of them.

The definition of "brand name" and "generic name" are acceptable and equivalent to Wisconsin.

The uses of "brand name" and "generic name" are then applied to labeling requirements:.

6.10(1) Required information. The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)." *[12/15/2004]*

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)"; *[12/15/2004]*

The Iowa rule in sub. (1) above does what AB 258 is attempting to do. It is phrased in similar fashion to various drafting attempts I had worked up.

Mentioning a "therapeutic interchange" under Wis. Stat. § 450.13, or Iowa doing it in its rule, really isn't necessary for purposes of labeling, under Wis. Stat. § 450.11. (In this sense the Iowa rule describing the drug product as "equivalent" is not really necessary under its labeling rule either). For Wisconsin purposes either a valid lawful substitution was made or it wasn't. So to be lawful, in Wisconsin the substitution must meet the requirement of section 450.13 for therapeutic equivalence. Labeling is a separate issue that should be addressed separately.

However, in terms of what the label should read, the Iowa rule does get it right, and the concept is along the lines that AB 258 should follow.

I would suggest using the nomenclature of "generic" and "brand"name, for purposes of labeling only, as Chapter 450 already uses them, and they are in common regulatory parlance both Federally and in other states, (ie..Iowa). This will meet common expectations for consumers and provide consistency for practitioners in this and other states who will be working from a common set of regulatory nomenclature regarding the terms "generic" and "brand" for purposes of labeling.

3. Suggestion for AB 258

Section 2. 450.11 (4) (c) of the statutes is created to read:

450.11 (4) (c) In addition to the information required under par. (a), if a pharmacist dispenses a generic name drug product for a prescribed brand name drug product, the pharmacist may include a statement on the label identifying the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)", unless the prescribing practitioner requests omission of the statement.

There is a remaining issue as I discussed with Mr. Sweet, and that is the related commonly occurring instance where no substitution is made, rather the practitioner writes a prescription order for a generic, and the patient is confused as to what the drug product is, and would like the "brand" name placed on the label. This second instance may have trademark implications as no lawful substitution has taken place, so no lawful reference is being made to the substituted out drug. Rather, the generic is "trading" on the association with a brand name that was never prescribed in the first instance nor dispensed. Similar drafting could be done to allow for labeling in this instance along the lines outlined above, with care taken to show that no substitution has in fact occurred. (and thinking carefully about the trademark issue)

**********Final note-

I have not used or addressed sub. (2) of the Iowa rule, which provides:

> (2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)"; *[12/15/2004]*

This section is not germaine to AB 258, because it describes a scenario which can lawfully currently be labeled as "(brand name product) for (generic name)", under Wis. Admn. Code § Phar 7.03 which provides in part:

"The prescription label shall not contain the brand or generic name of any drug or drug product other than that actually dispensed."

Therefore, the brand name will have a permissible generic name that could go on a label as well, currently, in this instance.

A helpful table

Brand prescribed-> Generic selected, (based on therapeutic substitution) AB 258 applies

Generic prescribed-> Generic selected, (statute to allow a "brand" name on label- trademark issue)

Generic prescribed-> Brand selected, (Wis. Admn. Code § Phar 7.03 applies)

AB 258 drafting notes 8-10-05

8/23/05

Dick Sweet:
Intent is that consumer (not necessarily statute) incorporate consumer-friendly terms "brand name" and "generic"

DO not include provision that would allow pharmacist to put brand name on label for generic dispensed when practitioner prescribes generic.

State of Wisconsin
2005 – 2006 LEGISLATURE

LRBs0180/
CTS:
WLJ

In: 9/24/05
Due: soon

PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

ASSEMBLY SUBSTITUTE AMENDMENT ,

TO 2005 ASSEMBLY BILL 258

AN ACT ...; **relating to:** prescription drug labels.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.11 (4m) of the statutes is created to read:

450.11 **(4m)** BRAND NAME PERMITTED ON LABEL. (a) In this subsection:

1. "Brand name" has the meaning given in s. 450.12 (1) (a).

2. "Generic name" has the meaning given in s. 450.12 (1) (b).

3. "Therapeutic equivalent" has the meaning given in s. 450.13 (1).

(b) Subject to par. (c), if a pharmacist, pursuant to a prescription order that specifies a drug product by its brand name, dispenses the drug product equivalent of the drug product specified in the prescription order, the label required under sub. (4) (a) may include both the generic name of the drug product equivalent and the

brand name specified in the prescription order, unless the prescribing practitioner requests that the brand name be omitted from the label.

SECTION 2. Initial applicability.

(1) This act first applies to prescription orders issued on the effective date of this subsection.

(END)

LRB–0913/2
CTS:lmk:pg

2005 ASSEMBLY BILL 258

March 18, 2005 – Introduced by Representatives GIELOW, STRACHOTA, AINSWORTH, BALLWEG, BERCEAU, BIES, GOTTLIEB, GRONEMUS, HAHN, HINES, HUNDERTMARK, KESTELL, KREIBICH, F. LASEE, LOTHIAN, MOULTON, NASS, OTT, POCAN, UNDERHEIM, VAN ROY and MOLEPSKE, cosponsored by Senators ROESSLER and MILLER. Referred to Committee on Health.

AN ACT ***to amend*** 450.13 (1); and ***to create*** 450.01 (11m) and 450.11 (4) (c) of the statutes; **relating to:** prescription drug labels.

Analysis by the Legislative Reference Bureau

Under current law, a pharmacist may dispense a drug product that has been designated by the federal Food and Drug Administration (FDA) as the therapeutic equivalent of the drug product that is prescribed (drug product equivalent), if the drug product equivalent is cheaper. Current law also requires a prescription drug label to specify certain information, including the name and address of the practitioner who prescribed the drug, the date on which the prescription was dispensed, the name of the patient, and directions for the use of the drug product or device.

This bill permits a pharmacist who dispenses a drug product equivalent to include a statement on the label identifying the prescribed drug product and indicating that the pharmacist has substituted a drug product equivalent, unless the prescribing practitioner requests omission of the statement.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.01 (11m) of the statutes is created to read: