

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Central Region
Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

FEI: 1000148065
3006489197

WARNING LETTER

August 25, 2009

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Joseph H. Lillard, President
Washington Homeopathic Products, Inc.
33 Fairfax Street
Berkeley Springs, WV 25411

Dear Mr. Lillard:

An inspection of your drug manufacturing facilities located in Berkeley Springs, WV at 2601 J R Hawvemale Way and 33 Fairfax Street conducted by our Food and Drug Administration (FDA) investigator from March 26-April 14, 2009, determined that you are a manufacturer of human, veterinary, and biological drug products. The inspection found significant violations from the Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals, Title 21, Code of Federal Regulations (CFR), Parts 210 and 211, with regard to the manufacture of homeopathic drug products made by your facility. These deviations reported by our investigator cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351 (a)(2)(B)].

In addition, this inspection, as well as our review of your website at the Internet address <http://www.homeopathyworks.com> in June 2009, also revealed that your firm is manufacturing and/or marketing unapproved drugs in violation of Sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)] and the drugs are also misbranded in violation of Sections 301(a), 502(a), 502(f)(1), and 503(b)(4) of the Act [21 U.S.C. §§ 331(a), 352(a), 352(f)(1), and 353(b)(4)].

We acknowledge receipt of your letters dated April 24, 2009, and have included comments below where appropriate. The violations we observed, include, but are not limited to, the following:

CGMP Deviations [§ 501(a)(2)(B)]

1) Your firm has not thoroughly investigated the failure of a batch or any of its components to meet specifications. Your firm did not extend the investigation of a failure of a batch or any of its components to other drug products that may have been associated with the specific failure or discrepancy [21 CFR § 211.192]. For example, unexplained discrepancies and/or an incomplete investigation was conducted or documented as follows:

a. Virex (Lot **(b)(4)**) was manufactured on July 23, 2008. A sample was collected and failed microbiological testing on July 30, 2008. A second sample was collected and failed microbiological testing on August 1, 2008. Then, a third sample was collected and it also failed microbiological testing on August 5, 2008. A fourth sample was collected and tested at your firm's 33 Fairfax Street laboratory on August 8, 2008. This fourth sample passed on August 10, 2008. Bulk Virex (Lot **(b)(4)**) was subsequently released and shipped on August 12, 2008. **(FS)**

Your response to the form FDA-483 failed to include justification as to why an investigation was not conducted regarding this batch of product that failed microbiological testing. Please explain your firm's scientific rationale for the testing scheme used, including why the first three tests were disregarded.

b. Broken glass was identified in filled 15 cc glass bottles of T-Gone Remedies Type 4 (lot **(b)(4)**) on January 20, 2009, during product filling operations. This lot was rejected and destroyed on January 29, 2009. "Deviation Report," dated January 22, 2009, stated: "Broken glass was in the prepackaged and sealed bottles from the distributor. No risks were involved. Product was pulled and destroyed on January 29, 2009. The broken glass inside the bottles accrued at the distributor's operation.

The drug product with the broken glass was destroyed and all other products that were used with that component was rechecked and all were all were clear." The investigation failed to identify other related products and lots manufactured with the implicated glass vials to assure no additional broken glass was present. Finally, the specific lot number of the problematic glass bottles (components) used to fill T-Gone Remedies Type 4 (lot **(b)(4)**) on January 20, 2009 was not documented in the investigation. **(HW)**

We note that your response to the form FDA-483 included the adding of lot numbers to your firm's batch records. However, your response did "not note if deviation reports would be revised to include review of additional implicated batches. It is important that all conclusions reached during an evaluation of production and control discrepancies be considered in the final review for release.

FDA has previously observed significant problems with the control of your manufacturing facilities, as documented on an FDA-483, Inspectional Observations, issued on November 6, 2007. Further, regarding the above noted microbial contamination incidents, as well as the serious and recurring CGMP observations documented during the current inspection, we are concerned about your lack of CGMP controls and your conclusions regarding investigations, retesting practices, and microbial testing. Please provide your rationale for the distribution of products that were implicated during the recent above-noted microbial contamination and broken glass incidents and manufactured under deficient CGMP conditions.

2) Your firm has not tested non-penicillin drug product for the presence of penicillin, when a reasonable possibility existed that a non-penicillin drug product has been exposed to a cross contamination with penicillin. The operations relating to the processing of penicillin are not performed in facilities separate from those used for other drug products [21 CFR §§ 211.176 and 211.42(e)]. There are no defined areas or such other control systems to prevent contamination for the handling and/or manufacturing of penicillin drug products.

For example, your firm lacked separate areas for manufacturing and separate control systems (e.g., air-handling systems) to prevent potential cross-contamination of penicillin residues during the manufacture of Penicillin C-Box homeopathic drug product. The manipulations of the Penicillin powder to manufacture Penicillin C-Box (lot **(b)(4)**) took place in an open area. In addition, your firm manufactured Ampicillin drug products (lots **(b)(4)** and **(b)(4)** in an open, undefined area which creates a potential risk of cross-contamination. **(FS)**

We acknowledge your commitment to cease manufacturing of products from

pharmaceuticals unless these products are monographed in the Homeopathic Pharmacopeia of the United States (HPUS). However, regarding the penicillin observation above, your response states: "The medicine manufactured was made from a dilute form of penicillin (diluted from one part in 100 parts of lactose)." Be advised that manufacturing penicillin from powder form to a liquid, even in small diluted quantities, presents a cross-contamination risk to other drug products and presents a major concern due to potential allergic reactions. Therefore, the risk of cross contamination from manufacturing penicillin, even in dilute form, is considered high. FDA expects manufacturers to implement measures necessary to prevent such cross-contamination. An assessment of the controls needed to prevent cross-contamination should be conducted by your firm. It is the responsibility of the manufacturer to prevent cross-contamination by physical separation with penicillin manufacturing operations and other drug products. Please explain what specific steps your firm will take to prevent cross-contamination of drug products with penicillin or other beta lactams.

3) Your firm did not reject any lot of components that did not meet the appropriate written specifications for identity, strength, quality and purity [21 CFR § 211.84(e)].

For example, a component that failed microbiological testing was used to manufacture a finished homeopathic drug product. Bulk Lanolin (lot **(b)(4)**) was tested on March 13, 2008 and passed on March 17, 2008. Bulk Lanolin lot was tested again on April 7, 2008, and failed microbiological testing on April 9, 2008. After incubating for 24 hours at 37°C, the sample appearance was observed on April 9, 2008 as "VERY black" and the testing log sheet states that the material was to be rejected. However, 24kg of bulk Lanolin lot **(b)(4)** was used to manufacture Calendula Homeopathic Ointment lot **(b)(4)** on June 4, 2008. Calendula Homeopathic Ointment lot **(b)(4)** passed release testing and 129 four ounce jars were released June 6, 2008. **(HW)**

Your response states: "In the future, when products are rejected, they will immediately be removed from the production area to an area in the warehouse where they cannot be used." We note that this response recognizes the need to quarantine rejected products to prevent future use. However, your response fails to state what other specific CGMP controls you will implement to ensure rejected drug products are not used again in the future (e.g., updated standard operating procedures; retraining; specific reject labeling; locked gates). Moreover, under 21 CFR § 211.84(d), the visual test is not an appropriate method to detect microbial contamination in your firm's components (e.g. bulk Lanolin).

This is a repeat observation from the November 2007 inspection.

4) Your firm did not withhold from use each lot of components until the lot has been sampled, tested, examined, and released by Quality Control [21 CFR § 211.84(a)].

Your firm is using materials dating back to the year 1991, without testing them. For example, all active homeopathic starting materials in inventory were assigned lot (b)(4), but there are no records to show the origin of lot (b)(4) or testing of any kind to verify the potency or identity. Further, Penicillin lot (b)(4) was used to manufacture Penicillin C-Box lot (b)(4), which was released on January 23, 2008; Valeriana lot (b)(4) was used to manufacture Valeriana lot (b)(4), which was released on April 18, 2008, and; Daphne lot (b)(4) was used to manufacture Daphne Indica lot (b)(4), which was released February 10, 2009.

Your response states: "Production workers have been instructed not to use any product with lot#(b)(4) in manufacturing, as QA will reject such product." This response is inadequate because you fail to address final disposition (e.g. destruction) of this untested lot. Please provide disposition records or indicate how you intend to destroy lot (b)(4). Further, regarding testing of all your components, your response failed to include details regarding supplier qualification or sampling of components. **(FS)**

This is a repeat observation from the November 2007 inspection.

5) Your firm has not established written procedures for production and process control designed to assure that drug products have the identity, strength, quality and purity that they are represented to possess [21 CFR § 211.100(a)]. For example, your firm has not conducted appropriate process validation studies for the following drug products: a) Prednisone, b) Lidocaine, c) Penicillin, d) TaurImmune Allergy Spray, e) Doxorubicin, f) Calendula Homeopathic Ointment, g) Influenza Remedy # 26, h) Keppra, and i) Rabies Vaccine.

It is essential that validation studies are conducted according to protocols specific to each product and process.

Your firm failed to identify process parameters, write validation protocols, and show that product performance is consistent and reproducible from batch-to-batch for your human drug products. After establishing a validated manufacturing process, you must follow your written procedures to maintain the process in a state of control. This requirement to establish and follow such procedures is ongoing over the life of the product/process, and incorporates an understanding that materials, equipment, production environment, personnel, and manufacturing procedures change. We acknowledge your April 24, 2009, commitment to complete validation studies for all of your products within six months. Please provide the latest status of validation activities for all of your drug products. **(FS)**

This is a repeat observation from the November 2007 inspection.

6) Your firm has not established written procedures for cleaning and maintenance of equipment [21 CFR § 211.67(b)].

For example, your firm failed to validate the cleaning process to demonstrate adequate cleaning of equipment used in manufacturing homeopathic drug products. Your firm uses non-dedicated laboratory equipment, including a (b)(4) Dispenser, pipette(s), succession vial, flask(s), and graduated cylinder(s), to manufacture Penicillin C-Box (lot (b)(4)). Other drug products that have been manufactured using this same drug manufacturing equipment include: Doxorubicin (lot (b)(4)); Silicea (lot (b)(4)); Daphne Indica (lot (b)(4)); and Rabies Vaccine (lots (b)(4) and (b)(4)). Validation studies have not been performed to verify that cleaning methods used to remove residues from non-dedicated equipment are effective. Further, the following additional homeopathic drug products were manufactured using non-dedicated equipment: Calendula Homeopathic Ointment; T-Gone Remedies Type 4; Virex; TaurImmune Allergy Spray; and Influenza Remedy #26. FDA is concerned about the risk of potential cross contamination of other drug products with penicillin due to your lack of cleaning validation.

Your response states "The process validation protocol for equipment cleaning has been done and the evaluation will be completed within 45 days." This response is inadequate because you failed to include the following: a) what manufacturing equipment would be included in the cleaning validation, b) description of residue testing and/or acceptance criteria, and c) what type of cleaning solutions would be utilized as part of the cleaning validation. **(FS)**

This is a repeat observation from the November 2007 inspection.

7) Failure of your firm to have a written assessment of stability of homeopathic drug products based at least on testing or examination of the drug product for compatibility of the ingredients and marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use [21 CFR § 211.166 (c)(1)]. For example, there have been no written assessments regarding the stability of excess homeopathic drug products stored in bulk containers. Specifically,

a) Children's Tonic (lot (b)(4)) was released on January 24, 2007, and excess finished product has been stored in a 1 gallon amber glass bottle. Excess finished homeopathic drug product is maintained and re-used to fill future orders.

b) Sore Throat (lot **(b)(4)**) was released October 31, 2007, and excess finished product has been stored in a 1 gallon clear glass bottle. Excess finished homeopathic drug product is maintained and re-used to fill future orders. **(HW)**

Your response is inadequate in that it fails to indicate any details (e.g. sample frequency, sample storage conditions, testing methods) or an updated procedure describing the future stability testing of your firm's bulk homeopathic drug products.

This is a repeat observation from the November 2007 inspection.

8) Your firm's written production and process control procedures were not followed in the execution of the various production and process control functions and were not documented at the time of performance [21 CFR § 211.100(b)]. For example, WHP-SOP # **(b)(4)**, "Stability Testing, II Rev. 1, Eff. 7/15/06, states that each year **(b)(4)** samples of major packaging systems will be stored and examined the following year for visible signs of deterioration. According to the procedure, these examinations are to be recorded and filed. Samples were collected in August 2007 and stored in the laboratory area. However, your firm failed to follow your written procedure in that there is no record that they were ever examined. No samples were collected in 2008. **(FS)**

Your response states that the above noted August 2007 stability packaging samples were reviewed and examined. However, you failed to provide any results of this review or if any signs of deterioration were noted from this examination. Further, your response states: "We have established a tickler system as a reminder of the August 2010 deadline." You failed to include a description of this "tickler system" and how it will ensure this required stability sampling is completed.

We also note that during the inspection you stated to our investigator that you pulled off the shelves certain non-homeopathic active ingredients and labeled these boxes "DO NOT USE" until your firm determined the proper disposition. Please provide documentation of the destruction of these non-homeopathic active ingredients.

Unapproved New Drugs [§§ 301(d) and 505(a)]

In addition to the CGMP violations, you manufacture and market unapproved new drugs in violation of the Act at your facilities located in Berkeley Springs, WV at 2601 Hawverdale Way and 33 Fairfax Street.

During the inspection, FDA collected your firm's labeling including labeling for the following products: Keppra 1-C TRIT, Keppra 5C, Keppra 6C, Keppra 11C, Keppra 12C, Keppra 29C, Keppra 30C, Keppra 196C, Keppra 199C, Keppra 20GC, Keppra 996C, Keppra 999C, Keppra 1M, Doxorubicin 5C, Doxorubicin 11 C, Doxorubicin 29C, Doxorubicin 30C, Doxorubicin 1C-TRIT, Prednisone 1C-TRIT, Prednisone 5C, Prednisone 6C, and Lidocaine 1C-TRIT, Lidocaine 5C, Lidocaine 11 C, Lidocaine 29C, Lidocaine 30C, Lidocaine 999C, Lidocaine 1M.

As labeled, the above products are drugs under section 201 (g)(1)(B) of the Act (21 U.S.C. § 321 (g)(1)(B)), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and under section 201 (g)(1)(C) of the Act (21 U.S.C. § 321 (g)(1)(C)) because they are intended to affect the structure or function of the body. Further, these products are new drugs within the meaning of section 201(p) of the Act (21 U.S.C. §321(p)) because they are not generally recognized as safe and effective for their labeled uses.

Under sections 301(d) and 505(a) of the Act (21 U.S.C. §§ 331(d) and 355(a)), a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or CD of the Act (21 U.S.C. § 355(b) or (j)) is in effect for the product. Based upon our information, there are no FDA-approved applications on file for the above products. The marketing of these products without an approved application constitutes a violation of these provisions of the Act.

We recognize that the labeling for these products identifies them as homeopathic drug products with active ingredients measured in homeopathic strengths. We acknowledge that many homeopathic drug products are manufactured and distributed without FDA approval under enforcement policies set out in FDA's Compliance Guide entitled, "Conditions Under Which Homeopathic Drugs May Be Marketed (CPG 7132.15)" (the CPG). The CPG defines a homeopathic drug as: "Any drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it, or its supplements."

Keppra, doxorubicin, prednisone, and lidocaine are not recognized active ingredients in the BPUS or any of its addenda or supplements. We note that Keppra is the proprietary name for an FDA-approved product containing the active pharmaceutical ingredient levetiracetam. Levetiracetam is also not a recognized active ingredient in the HPUS or any of its addenda or supplements. Furthermore, to our knowledge, none of these ingredients are listed in any recognized medical material containing information on the preparation of homeopathic medicines. Therefore, Keppra (levetiracetam), doxorubicin, prednisone, and lidocaine are not homeopathic ingredients and Keppra 1-C TRIT, Keppra

5C, Keppra 6C, Keppra 11C, Keppra 12C, Keppra 29C, Keppra 30C, Keppra 196C, Keppra 199C, Keppra 200C, Keppra 996C, Keppra 999C, Keppra 1M, Doxorubicin 5C, Doxorubicin 11 C, Doxorubicin 29C, Doxorubicin 30C, Doxorubicin 1C-TRIT, Prednisone 1C-TRIT, Prednisone 5C, Prednisone 6C, and Lidocaine 1C-TRIT, Lidocaine 5C, Lidocaine 11C, Lidocaine 29C, Lidocaine 30C, Lidocaine 999C, and Lidocaine 1M are not considered homeopathic drug products under the CPG. Accordingly, the policies set forth in the CPG for the marketing of homeopathic drug products do not apply to these products.

Misbranding [§§ 502(f)(1) and 502(a)]

Additionally, Keppra, doxorubicin, prednisone, and lidocaine are misbranded. Because of toxicity or potentiality for harmful effects, these products are not amenable for use by individuals who are not medical practitioners; adequate directions cannot be written for them so that a layman can use these products safely for their intended uses.

Consequently, their labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)). Because your products lack required approved applications, they are not exempt under 21 C.F.R. § 201.115 from the requirements of section 502(f)(1) of the Act. The introduction or delivery for introduction into interstate commerce of these products therefore violates sections 301(a) and (d) of the Act (21 U.S.C. §§ 331(a) and (d)).

Furthermore, these products are misbranded under section 502(a) of the Act (21 U.S.C. §352(a)) because the labeling of Keppra 1-C TRIT, Keppra 5C, Keppra 6C, Keppra 11C, Keppra 12C, Keppra 29C, Keppra 30C, Keppra 196C, Keppra 199C, Keppra 200C, Keppra 996C, Keppra 999C, Keppra 1M, Doxorubicin 5C, Doxorubicin 11C, Doxorubicin 29C, Doxorubicin 30C, Doxorubicin 1C-TRIT, Prednisone 1C-TRIT, Prednisone 5C, Prednisone 6C, and Lidocaine 1CTRIT, Lidocaine 5C, Lidocaine 11 C, Lidocaine 29C, Lidocaine 30C, Lidocaine 999C, and Lidocaine 1M is false and misleading. The products labeling includes the term "HPUS." According to the labeling guidelines established by the Homeopathic Pharmacopeia of the United States (HPUS), "the designation 'HPUS' is restricted (or may be appended only) to those substances (or Homeopathic Drug Products) whose monographs have been reviewed by the Convention and have been approved for publication in the current Pharmacopeia by the Board of Directors." As stated above, Keppra (levetiracetam), doxorubicin, prednisone, and lidocaine are not recognized active ingredients in the HPUS or any of its addenda or supplements, and therefore listing "HPUS" on the labeling of these products is false and misleading. The labeling of your products Keppra 1-C TRIT, Keppra 5C, Keppra 6C, Keppra 11C, Keppra 12C, Keppra 29C, Keppra 30C, Keppra 196C, Keppra 199C, Keppra 200C, Keppra 996C, Keppra 999C, and Keppra 1M is also false and misleading because it erroneously suggests that the products contain Keppra, which is the proprietary name for an FDA-approved product containing the active pharmaceutical ingredient levetiracetam. Regardless of whether your products contain levetiracetam, you are not the

sponsor of the approved application for Keppra, and it is false and misleading to suggest that your products are manufactured by that sponsor.

Misbranding [§§ 503(b)(4), and 301(a)]

FDA reviewed your website at the Internet address <http://www.homeopathyworks.com> in June 2009. FDA reviewed your firm's labeling and marketing information for homeopathic products including but not limited to: Guaiacum, Abrotanum, Dna, and Aurum iodatum. As presently labeled, these products are misbranded under Sections 503 and 301 of the Act (21 U.S.C. §§353 and 331), as described below.

Your online product catalog documents the intended uses of these products as follows:

Guaiacum: "Rheumatism"

Abrotanum: "Gout"

Dna: "Learning difficulty"

Aurum iodatum: "Senility"

Based on the above labeling and claims, these products are drugs under section 201 (g)(1)(B) of the Act (21 U.S.C. § 321(g)(1)(B)), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and under section 201 (g)(1)(C) of the Act (21 U.S.C. § 321 (g)(1)(C)), because they are intended to affect the structure or any function of the body.

Section 503(b)(1) of the Act (21 U.S.C. 353(b)(1)) identifies criteria for determining the prescription status of a product. The products listed above are prescription drugs within the meaning of section 503(b)(1) of the Act because they are intended to treat diseases that require diagnosis and treatment by a physician or are intended to provide treatment for symptoms usually caused by an underlying disease process that requires diagnosis and treatment by a physician. Because they may be dispensed only by prescription of a licensed practitioner, these products are misbranded under Section 503(b)(4) of the Act (21 U.S.C. § 353(b)(4)) in that their labels fail to bear the symbol, "Rx only"² Section 301(a) of the Act prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded, and thus your marketing of these misbranded products violates Section 301(a) of the Act (21 U.S.C. §§ 331(a)).

We recognize that these products are labeled as homeopathic drugs with active ingredients measured in homeopathic strengths.³ Homeopathic drugs are subject to the same regulatory requirements as other drugs; nothing in the Act exempts homeopathic drugs from any of the requirements related to adulteration, labeling, misbranding, or

approval. The CPG identifies specific conditions under which homeopathic drugs may ordinarily be marketed; thus, in order to fall under the enforcement policies set forth in the CPG, a homeopathic product must meet the conditions set forth in the CPG. One of those conditions is compliance with Section 503(b) of the Act. Under the CPG, only homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC. Homeopathic products offered for conditions not amenable to OTC use must be marketed as prescription products.⁴

The violations cited in this letter are not intended to be an all-inclusive statement of the objectionable conditions that exist at your facility. You are responsible for investigating and determining the causes of the objectionable conditions identified above and for preventing their recurrence or the occurrence of other objectionable conditions. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. A reinspection may be necessary.

Due to the severity of the violations and the inadequate FDA-483 responses, we are requesting that you and/or your representatives come into the Baltimore District Office for a meeting and present your corrective action plan to FDA. Within five working days, please contact Randy Pack at the number below to schedule this meeting to outline the specific steps you have taken or are taking to correct these violations.

Your reply should be directed to Randy F. Pack, Compliance Officer, Food and Drug Administration, Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. If you have any questions, please do not hesitate to contact Mr. Randy F. Pack at (410) 779-5454, extension 417.

Sincerely,
/S/

Evelyn Bonnin
District Director

1 Homeopathic Pharmacopoeia Convention of the United States. Homeopathic Pharmacopoeia of the United States [Internet]. Southeastern, PA: HPCUS; 2004. Available from http://www.hpus.com/online_database/index.php.

2 The CPG states that prescription homeopathic products "must bear the prescription legend, 'Caution: Federal law prohibits dispensing without prescription,' in conformance with Section 503(b)(1) of the Act." The CPG was adopted by the agency in 1988. In 1997, Congress enacted the FDA Modernization Act (FDAMA) (Public Law 105-115); section 126 of FDAMA amended Section 503(b)(1)(4) of the Act to require that the label of a prescription drug product bear, at a minimum, the symbol "Rx only."

3 For example, one of your Aurum Iodatum products is labeled as Aurum iodatum 13x.

4 We note that the CPG also states that, if the HPUS specifies a distinction between nonprescription (OTC) and prescription status of a product based on strength (e.g., 30X), and that distinction is more restrictive than section 503(b) of the Act, the more stringent criteria i.e., the HPUS criteria) will apply. It follows from this that, if the HPUS specifies a distinction between GTC and prescription status based on strength, and that distinction is less restrictive than section 503(b) of the Act, the section 503(b) criteria will apply regardless of the HPUS distinction.