

September 25, 2015

Express Mail

Richard Russell
President and CEO
Greer Laboratories, Inc.
639 Nuway Circle, NE
Lenoir, North Carolina 28645

Dear Mr. Russell:

Through routine monitoring and surveillance, the Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research of the United States Food and Drug Administration (FDA) has reviewed your website www.greerlabs.com as well as other information in our records concerning licensed non-standardized allergenic extracts used in the diagnosis and treatment of allergic disease. It has come to our attention that correct and consistent nomenclature is not being used, and that the proportions of non-standardized extracts used in licensed allergen mixtures are not identified. The Federal Food, Drug, and Cosmetic Act provides that a drug, including an allergenic extract, shall be deemed to be misbranded if its labeling is false or misleading in any particular (Section 502(a) Federal Food, Drug, and Cosmetic Act) [21 U.S.C. 352 (a)]. Such a product may also be misbranded if the contents are not described with adequate specificity, as required under regulation (21 CFR 610.14, 610.61, 680.1(b)) and statute [21 U.S.C. 352(c), 352(e)(1)(A)(ii)].

The use of incorrect nomenclature, or multiple descriptors for allergenic extracts derived from the same source material, can lead to mistakes in diagnosis and inappropriate treatment of allergies. For example, an adverse reaction could result if two allergenic extracts identified using inconsistent nomenclature actually contain the same allergen and are administered to the same individual. In addition, the inaccurate identification of the proportions of non-standardized extracts used to make licensed allergen mixtures can lead to mistakes in the diagnosis and inappropriate treatment of allergies. Consistent use of identifying terminology and correct identification of the proportions of each non-standardized extract used to make licensed allergen mixtures are necessary to assure that allergenic extracts are accurately labeled and not misbranded.

Reviews by external panels of data related to the safety, effectiveness, and labeling for non-standardized allergenic extracts took place in 1974-1979 and 1982-1983 and support

the use of full and accurate nomenclature. The first panel's report included the proposal that specific designations and identifiers for the source materials be used and that these appear on the product label for all allergenic extracts. The second panel reviewed the findings of the first panel and further specified that genus/species names be used to identify pollen, mold and plant extracts.

FDA formed an internal committee to review available scientific and medical data from published literature on the safety and effectiveness of non-standardized allergenic extracts. During this review, FDA determined that nomenclature was not consistently applied. For example:

- Information on specific species cannot be ascertained because some products are identified using the term “mixed¹”
- Manufacturers have multiple listings in the licenses for allergenic extracts derived from the same source material
- The adoption of a different naming convention for the same source material of a specific genus and species licensed by another manufacturer
- The identity of the extract is listed by genus only, so different species may be represented across manufacturers.

This review became the basis for the nomenclature provided in this letter (see Attachments) to fully and accurately identify licensed non-standardized allergenic extracts. Technology is readily available to accurately identify the species of all source materials used for allergenic extract manufacture, so that valid nomenclature can be applied to non-standardized allergenic extracts. As described in this letter (see Attachments), FDA has provided proper identifiers for source materials that, if consistently used, would accurately identify non-standardized allergenic extracts derived from these materials.

Additionally, the identification of licensed mixtures of non-standardized allergenic extracts is ambiguous and leads to confusion and potentially inappropriate use of these extracts in the diagnosis and treatment of allergic disease. Frequently a product is identified by genus only and the species is unknown. Also, even when the component species used to manufacture the licensed allergen mixture are identified, the proportions of each non-standardized extract used to make the licensed allergen mixture are not identified. This inaccurate identification of the proportions of each non-standardized extract used in these licensed allergen mixtures also leads to confusion and potentially inappropriate treatment of allergies.

¹ Under 21 CFR 610.17, licensed biological products must not be combined with other licensed biological products “either therapeutic, prophylactic or diagnostic,” except as covered by a license obtained for the combined product. All mixes of allergenic extracts, including custom mixes, must be subject of an approved biologics license application or have in effect an investigational new drug application. FDA is addressing prescription sets of allergenic extracts in separate guidance. See Draft Guidance for Industry, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application. <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm434176.pdf>

The nomenclature identifiers provided in this letter (see Attachments) do not necessarily constitute an exhaustive list of your products used in the diagnosis and treatment of allergic disease. It is your responsibility to ensure that the labeling for all of your licensed biological products accurately identifies the products and complies with all applicable laws, regulations, and standards.

Please review the nomenclature identifiers provided in this letter (see Attachments) and notify this office, in writing, of: (1) the steps you have taken or will take to properly identify the non-standardized allergenic extracts that are not identified, or properly identify the proportions of non-standardized extracts used to make licensed allergen mixtures, or both, based on the nomenclature provided in this letter; (2) your proposed timeframes for submitting labeling supplements under 21 CFR 601.12(f)(2)(i)(E) for product labeling that needs revision; and (3) your plans to update your establishment registration and product listing information including all currently manufactured products under Section 510 of the Act [21 U.S.C. 360]. Your response should be sent to me at the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Avenue, WO71-5030, Silver Spring, Maryland, 20993-0002.

In addition, please identify any non-standardized allergenic extracts that you have discontinued manufacturing and have no plans to manufacture in the future. For those non-standardized allergenic extracts that you no longer manufacture or intend to manufacture, if any, we ask you to consider submitting a voluntary request that your biologics license be revoked with regard to those extracts.

If you have questions concerning this matter, you may contact me at (240)-402-9153. Additionally, you may contact Dr. Jay Slater, Director, Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review at (240)-402-7396.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Attachments:

Table 1 – Licensed non-standardized allergenic extracts with incorrect identifiers and recommended correct identifiers

Table 2 – Licensed non-standardized allergenic extracts with correct identifiers

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Mark Hites

Authorizing Official

Greer Laboratories, Inc.

639 Nuway Circle, NE

Lenoir, North Carolina 28645

Greer. Table 1: Licensed non-standardized allergenic extracts with incorrect identifiers and recommended correct identifiers

Current identifier	Recommended identifier	Explanation
Animal Allergens, Canary Feathers <i>Serinus canarius</i>	Animal Allergens: Canary feathers, <i>Serinus canaria canarius</i>	The scientific name is misspelled. The common name is correct.
Animal Allergens, Cattle Epithelium, <i>Bos sp.</i>	Animal Allergens: Cattle epithelium , <i>Bos taurus</i>	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Chicken Feathers <i>Gallus sp.</i>	Animal Allergens: Chicken feathers, <i>Gallus gallus</i>	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Dog Epithelium <i>Canis familiaris</i>	Animal Allergens: Dog Epithelium, <i>Canis lupus familiaris</i>	The scientific name is incorrect. The common name is correct.
Animal Allergens, Duck Feathers <i>Anas platyrhynchos</i>	Animal Allergens: Duck Feathers, <i>Anas platyrhynchos</i>	The scientific name is misspelled. The common name is correct.
Animal Allergens, Feathers, mixed (chicken, duck, goose)	Animal Allergens: Feathers, mixed (chicken, duck, goose), (species to be specified)	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Goose Feathers <i>Anser domesticus</i>	Animal Allergens: Goose Feathers, <i>Anser</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Guinea Pig Epithelia <i>Cavia porcellus</i>	Animal Allergens: Guinea Pig Epithelia, <i>Cavia porcellus</i>	The scientific name is misspelled. The common name is correct.
Animal Allergens, Parakeet Feathers <i>Psittacidae</i>	Animal Allergens: Parakeet Feathers, (species to be specified)	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Silk	Animal Allergens: (common name and source material to be specified), <i>Bombyx mori</i>	The scientific name is absent. The common name should be revised to indicate that the source material is silk worm cocoons and not processed silk material.
Food - Animal Products and Poultry Products, Beef <i>Bos sp</i>	Food - Animal Products and Poultry Products: Beef, <i>Bos taurus</i>	The scientific name is ambiguous. The common name is correct.
Food - Animal Products and Poultry Products, Chicken Meat <i>Gallus sp.</i>	Food - Animal Products and Poultry Products: Chicken Meat, <i>Gallus gallus</i>	The scientific name is ambiguous. The common name is correct.
Food - Animal Products and Poultry Products, Egg, White <i>Gallus sp.</i>	Food - Animal Products and Poultry Products: Egg, white , <i>Gallus gallus</i>	The scientific name is ambiguous. The common name is correct.
Food - Animal Products and Poultry Products, Egg, Whole <i>Gallus sp.</i>	Food - Animal Products and Poultry Products: Egg, whole , <i>Gallus gallus</i>	The scientific name is ambiguous. The common name is correct.
Food - Animal Products and Poultry Products, Egg, Yolk <i>Gallus sp.</i>	Food - Animal Products and Poultry Products: Egg, yolk , <i>Gallus gallus</i>	The scientific name is ambiguous. The common name is correct.
Food - Dairy Products, Milk, Whole Cow's	Food - Dairy Products: Milk , <i>Bos taurus</i>	The scientific name is absent. The common name is correct.
Food - Fish and Shellfish, Clam <i>Mya mercenaria</i>	Food - Fish and Shellfish: Clam, <i>Mercenaria mercenaria</i>	The scientific name is correct. The common name, <i>Mya Clam</i> , is not correct.
Food - Fish and Shellfish, Codfish <i>Gadus callarias</i>	Food - Fish and Shellfish: Cod, Atlantic, <i>Gadus morhua</i>	The scientific name is obsolete. The common name is ambiguous.
Food - Fish and Shellfish, Crab <i>Callinectes sapidus</i>	Food - Fish and Shellfish: Crab, Blue, <i>Callinectes sapidus</i>	The scientific name is correct. The common name is ambiguous.
Food - Fish and Shellfish, Flounder <i>Platichthys sp.</i>	Food - Fish and Shellfish: Flounder, <i>Platichthys flesus</i>	The scientific name is ambiguous. The common name is correct.
Food - Fish and Shellfish, Herring <i>Clupea sp.</i>	Food - Fish and Shellfish: Herring, <i>Clupea</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Food - Fish and Shellfish, Oyster <i>Ostrea spp.</i>	Food - Fish and Shellfish: Oyster, <i>Ostrea</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Food - Fish and Shellfish, Perch <i>Sebastes marinus</i>	Food - Fish and Shellfish:(common name to be specified), (species to be specified)	The scientific name is obsolete. The common name is ambiguous.
Food - Fish and Shellfish, Scallops <i>Pecten magellanicus</i>	Food - Fish and Shellfish: Scallop, Sea, <i>Placopecten magellanicus</i>	The scientific name is obsolete. The common name is ambiguous.

Greer. Table 1: Licensed non-standardized allergenic extracts with incorrect identifiers and recommended correct identifiers

Food - Fish and Shellfish, Shrimp Penaeus sp.	Food - Fish and Shellfish: Shrimp, Penaeus (species to be specified)	The scientific name is ambiguous. The common name is correct.
Food - Fish and Shellfish, Trout, Lake Salvelinus sp.	Food - Fish and Shellfish: Trout, Lake, Salvelinus (species to be specified)	The scientific name is ambiguous. The common name is correct.
Food - Fish and Shellfish, Tuna Thunnus sp.	Food - Fish and Shellfish: Tuna, Thunnus (species to be specified)	The scientific name is ambiguous. The common name is correct.
Food - Plant Source, Banana Musa paradisiaca	Food - Plant Source: Banana, Musa (species to be specified)	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Blueberry Vaccinium canadense	Food - Plant Source: Blueberry, Velvetleaf, Vaccinium myrtilloides	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Broccoli Brassica botrytis (or oleracea var. botrytis)	Food - Plant Source: Broccoli, Brassica oleracea var. botrytis	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Cabbage Brassica capitata (or oleracea var. capitata)	Food - Plant Source: Cabbage, Brassica oleracea var. capitata	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Cantaloupe (Muskmelon) Cucumis melo	Food - Plant Source: Cantaloupe, Cucumis melo	The scientific and common names are correct. Cantaloupe is a cultivar of muskmelon (C. melo). Cantaloupe is a variant spelling.
Food - Plant Source, Cauliflower Brassica oleracea (or oleracea var. botrytis)	Food - Plant Source: Cauliflower, Brassica oleracea var. botrytis	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Cherry Prunus sp.	Food - Plant Source: Cherry, Prunus (species to be specified)	The scientific name is ambiguous. The common name is correct.
Food - Plant Source, Grape, White Seedless Vitis sp. (or Vitis vinifera)	Food - Plant source: Grape, White, Vitis (species to be specified)	The scientific name is ambiguous. The common name is correct.
Food - Plant Source, Grapefruit Citrus unvavcarpa	Food - Plant Source: Grapefruit, Citrus X paradisi	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Lemon Citrus limon	Food - Plant Source: Lemon, Citrus X limon	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Malt Hordeum vulgare	Food - Plant Source: Malt (Barley), Hordeum vulgare	The scientific name is correct. The common name is ambiguous.
Food - Plant Source, Mustard Seed Brassica spp.	Food - Plant Source: Mustard seed, Brassica (species to be specified)	The scientific name is ambiguous. The common name is correct.
Food - Plant Source, Nutmeg Myristica fragrans	Food - Plant Source: Nutmeg, Myristica fragrans	The scientific name is misspelled. The common name is correct.
Food - Plant Source, Onion Allium cepa (or cepa var. cepa)	Food - Plant Source: Onion, Allium cepa	The scientific name is ambiguous. The common name is correct.
Food - Plant Source, Orange Citrus sinensis	Food - Plant Source: Orange, Citrus X sinensis	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Pecanarya Carya illinoensis	Food - Plant Source: Pecan, Carya illinoensis	The scientific name is misspelled. The common name is correct.
Food - Plant Source, Sesame Seed Sesamum orientale	Food - Plant Source: Sesame seed, Sesamum indicum	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Squash, Yellow Summer Cucurbita pepo melopepo	Food - Plant Source: Squash, Yellow Summer, Cucurbita pepo var. ovifera	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Strawberry Fragaria chilloensis	Food - Plant Source: Strawberry, Fragaria X ananassa	The scientific name is incorrect. The common name is correct.
Food - Plant Source, Tomato Lycopersicon esculentum	Food - Plant Source: Tomato, Solanum lycopersicum	The scientific name is obsolete. The common name is correct.
Food - Plant Source, Vanilla Vanilla fragrans	Food - Plant Source: Vanilla, Vanilla planifolia	The scientific name is obsolete. The common name is correct.
Insects (Whole Body), Caddis Fly Trichoptera sp.	Insects (Whole Body): Caddis Fly, Trichoptera (species to be specified)	The scientific name is ambiguous. The common name is correct.
Insects (Whole Body), Cockroach German Blatella germanica	Insects (Whole Body): , Blattella germanica	The scientific name is misspelled. The common name is correct.

Greer, Table 1: Licensed non-standardized allergenic extracts with incorrect identifiers and recommended correct identifiers

Insects (Whole Body), Deer Fly Chrysops sp.	Insects (Whole Body): Deer fly, Chrysops (species to be specified)	The scientific name is ambiguous. The common name is correct.
Insects (Whole Body), Flea Ctenocephalis canis	Insects (Whole Body): Flea, Ctenocephalides canis	The scientific name is misspelled. The common name is correct.
Insects (Whole Body), Flea Ctenocephalis felis	Insects (Whole Body): Flea, Ctenocephalides felis	The scientific name is misspelled. The common name is correct.
Insects (Whole Body), Mayfly Ephemerida sp.	Insects (Whole Body): Mayfly, (genus and species to be specified)	The scientific name is ambiguous. The common name is correct.
Insects (Whole Body), Moth Heterocera Molds, Rusts and Smuts, Acremonium strictum	Insects (Whole Body): Moth, (genus and species to be specified) Molds, Rusts and Smuts: Sarocladium strictum	The scientific name is ambiguous. The common name is correct. Scientific name is obsolete.
Molds, Rusts and Smuts, Alternaria tenuis (alternata)	Molds, Rusts and Smuts: Alternaria alternata	Scientific name is obsolete.
Molds, Rusts and Smuts, Aspergillus amsterdami	Molds, Rusts and Smuts: , Aspergillus amstelodami	Scientific name is misspelled.
Molds, Rusts and Smuts, Barley Smut, Loose Ustilago nuda	Molds, Rusts and Smuts: (common name to be specified), Ustilago nuda	Scientific name is correct. Common name is uncertain.
Molds, Rusts and Smuts, Drechslera spicifera	Molds, Rusts and Smuts: Curvularia spicifera	Scientific name is obsolete.
Molds, Rusts and Smuts, Fusarium moniliforme	Molds, Rusts and Smuts: Gibberella fujikuroi	Scientific name is obsolete.
Molds, Rusts and Smuts, Johnson Grass Smut Sphaerotheca cruenta	Molds, Rusts and Smuts: (common name to be specified), Sporisorium cruentum	Scientific name is obsolete. Common name is uncertain.
Molds, Rusts and Smuts, Oat Stem Smut Molds, Rusts and Smuts, Paecilomyces varioti	Molds, Rusts and Smuts: Oat Stem Smut, (genus and species to be specified) Molds, Rusts and Smuts: Paecilomyces varioti	Scientific name is ambiguous. Scientific name is misspelled.
Molds, Rusts and Smuts, Rhizopus oryzae	Molds, Rusts and Smuts: Rhizopus arrhizus	Scientific name is obsolete.
Molds, Rusts and Smuts, Wheat Smut, Loose Ustilago tritici	Molds, Rusts and Smuts: (common name to be specified), Ustilago tritici	Scientific name is correct. Common name is uncertain.
Molds, Rusts and Smuts, Wheat Stem Rust Puccinia graminis tritici	Molds, Rusts and Smuts: Puccinia (species to be specified)	Scientific name is ambiguous.
Plants and Plant Parts, Cotton Linters	Plants and Plant Parts: Cotton linters, Gossypium (species to be specified)	The scientific name is ambiguous. The common name is correct.
Plants and Plant Parts, Cottonseed Gossypium spp.	Plants and Plant Parts: Cottonseed, Gossypium (species to be specified)	The scientific name is ambiguous. The common name is correct.
Plants and Plant Parts, Flaxseed or Linseed Linum usitatissimum	Plants and Plant Parts: Flax, Linum usitatissimum	The scientific name is correct. The common name is ambiguous.
Plants and Plant Parts, Gum, Acacia or Arabic Acacia senegal	Plants and Plant Parts: Gum, Arabic, Acacia senegal	The scientific name is correct. The common name is ambiguous.
Plants and Plant Parts, Gum, Karaya or Bassora Cochlospermum religiosum	Plants and Plant Parts: Gum (Karaya or Bassora), Silk-cotton Tree, Cochlospermum religiosum	The scientific name is correct. The common name is ambiguous.
Plants and Plant Parts, Orris Root Iris florentina	Plants and Plant Parts: Orris root, Iris germanica	The scientific name is obsolete. The common name is correct.
Plants and Plant Parts, Pyrethrum Chrysanthemum spp.	Plants and Plant Parts: Pyrethrum, Chrysanthemum cinerariifolium	The scientific name is ambiguous. The common name is correct.
Plants and Plant Parts, Tobacco, Leaf Pollens - Cultivated Farm Plants, Barley Pollens - Cultivated Farm Plants, Clover, Red Trifolium communis	Plants and Plant Parts: Tobacco, Cultivated, Leaf, Nicotiana tabacum Pollens - Cultivated Farm Plants: Barley, Hordeum vulgare Pollens - Cultivated Farm Plants: Clover, Red, Trifolium pratense	The scientific name is absent. The common name is correct. The scientific name is absent. The common name is correct. The scientific name is obsolete. The common name is correct.
Pollens - Cultivated Farm Plants, Mustard, Brassica sp	Pollens - Cultivated Farm Plants: Mustard, Brassica (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Cultivated Farm Plants, Wheat, Cultivated Triticum sativa	Pollens - Cultivated Farm Plants: Wheat, Cultivated, Triticum aestivum	The scientific name is obsolete. The common name is correct.
Pollens - Flowers, Aster Aster sp.	Pollens - Flowers: (common name to be specified), Aster (species to be specified)	The scientific and common names are ambiguous.

Greer. Table 1: Licensed non-standardized allergenic extracts with incorrect identifiers and recommended correct identifiers

Pollens - Flowers, Daisy Chrysanthemum leucanthemum	Pollens - Flowers: Daisy, <i>Leucanthemum vulgare</i>	The scientific name is obsolete. The common name is correct.
Pollens - Grasses, Quack (Couch) Grass	Pollens - Grasses: Quack (Couch) Grass, <i>Elymus repens</i>	The scientific name is obsolete. The common name is correct.
Agropyron repens	Pollens - Grasses: Wheatgrass, Western, <i>Pascopyrum smithii</i>	The scientific name is obsolete. The common name is correct.
Agropyron smithii	Pollens - Trees: Acacia spp.	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Alder, Tag-Smooth	Pollens - Trees: Alder, Tag-Smooth, <i>Alnus incana</i> ssp. <i>rugosa</i>	The scientific name is obsolete. The common name is correct.
<i>rugosa</i>	Pollens - Trees: Ash, Oregon Fraxinus	The scientific name is obsolete. The common name is correct.
<i>oregona</i>	Pollens - Trees: Bayberry <i>Myrica cerifera</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Beefwood-Australian Pine	Pollens - Trees: Beefwood-Australian Pine, <i>Casuarina equisetifolia</i>	The scientific name is misspelled. The common name is correct.
<i>Casuarina equisetifolia</i>	Pollens - Trees: Birch, Mix <i>Betula</i> spp.	The scientific and common names are ambiguous.
Pollens - Trees, Cottonwood, Fremont	Pollens - Trees: Cottonwood, Fremont, <i>Populus fremontii</i>	The scientific name is misspelled. The common name is correct.
<i>Populus fremontii</i>	Pollens - Trees: Cottonwood, Rio Grande,	The scientific name is obsolete. The common name is correct.
<i>Populus wislizeni</i>	Pollens - Trees: Cottonwood, Western, <i>Populus deltoides</i> ssp. <i>wislizeni</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Cottonwood, Western	Pollens - Trees: Cottonwood, Western, <i>Populus deltoides</i> ssp. <i>Monilifera</i>	The scientific name is obsolete. The common name is correct.
<i>Populus sargentii</i>	Pollens - Trees: Cypress, Arizona	The scientific name is obsolete. The common name is correct.
<i>Cupressus arizonica</i>	Pollens - Trees: Hickory, White, <i>Carya tomentosa</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Hickory, White <i>Carya alba</i>	Pollens - Trees: Juniper, Pinchot, <i>Juniperus pinchotii</i>	The scientific name is misspelled. The common name is correct.
Pollens - Trees, Juniper, Pinchot <i>Juniperus pinchotii</i>	Pollens - Trees: Mango Blossom <i>Mangifera</i> (species to be specified)	The scientific name is misspelled. The common name is correct.
<i>pinchotii</i>	Pollens - Trees: Maple, Coast	The scientific name is absent. The common name is correct.
sp.	Pollens - Trees: Mesquite <i>Prosopis juliflora</i> (<i>glandulosa</i>)	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Mesquite <i>Prosopis juliflora</i> (<i>glandulosa</i>)	Pollens - Trees: Oak, Arizona Scrub, <i>Quercus chrysolepis</i>	The scientific name is misspelled. The common name is correct.
Pollens - Trees, Oak, Arizona Scrub	Pollens - Trees: Oak, California Black, <i>Quercus kelloggii</i>	The scientific name is obsolete. The common name is correct.
<i>Quercus chrysolepis</i>	Pollens - Trees: Orange Citrus <i>sinensis</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Oak, California Black	Pollens - Trees: Palm, Queen, <i>Syagrus romanzoffiana</i>	The scientific name is obsolete. The common name is correct.
<i>Quercus kelloggii-californica</i>	Pollens - Trees: Pine, Mix <i>Pinus</i> spp.	The scientific and common names are ambiguous.
Pollens - Trees, Orange Citrus <i>sinensis</i>	Pollens - Trees: Poplar, Lombardy <i>Populus nigra italica</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Palm, Queen <i>Arecastrum romanzoffianum</i>	Pollens - Trees: Sycamore, American (Eastern), <i>Platanus occidentalis</i>	The scientific name is misspelled. The common name is correct.
Pollens - Trees, Pine, Mix <i>Pinus</i> spp.	Pollens - Trees: Willow, Arroyo, <i>Salix lasiolepis</i>	The scientific name is misspelled. The common name is correct.
Pollens - Trees, Poplar, Lombardy <i>Populus nigra italica</i>	Pollens - Weeds and Garden Plants, (common name to be specified), <i>Baccharis</i> spp.	The scientific names are ambiguous. The common name is absent.
Pollens - Trees, Sycamore, American (Eastern) <i>Platanus occidentalis</i>	Pollens - Weeds and Garden Plants: Burro Brush (Greasebush), <i>Ambrosia salsola</i>	The scientific name is misspelled. The common name is correct.
Pollens - Trees, Willow, Arroyo <i>Salix lasiolepis</i>	Pollens - Weeds and Garden Plants: Cocklebur, <i>Xanthium strumarium</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, <i>Baccharis</i> spp.		
Pollens - Weeds and Garden Plants, Burro Brush <i>Hymenoclea salsola</i> (Greasebush)		
Pollens - Weeds and Garden Plants, Cocklebur <i>Xanthium commune</i>		

Greer. Table 1: Licensed non-standardized allergenic extracts with incorrect identifiers and recommended correct identifiers

Pollens - Weeds and Garden Plants, Hemp, Western Water Acnida tamariscina	Pollens - Weeds and Garden Plants: Hemp, Western Water, Amaranthus tuberculatus	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Jerusalem Oak Chenopodium botrys	Pollens - Weeds and Garden Plants: Jerusalem Oak, Dysphania botrys	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Marshelder, Burweed (Giant Poverty) Iva xanthifolia	Pollens - Weeds and Garden Plants: Marshelder, Burweed (Giant Poverty), Cyclachaena xanthifolia	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Marshelder, True (Rough) Iva ciliata	Pollens - Weeds and Garden Plants: Marshelder, True (Rough), Iva annua	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Nettle Urtica dioica	Pollens - Weeds and Garden Plants: Nettle, Urtica dioica	The scientific name is misspelled. The common name is correct.
Pollens - Weeds and Garden Plants, Palmer's Amaranth Amaranthus palmeri	Pollens - Weeds and Garden Plants: Palmer's Amaranth, Amaranthus palmeri	The scientific name is misspelled. The common name is correct.
Pollens - Weeds and Garden Plants, Rabbit Bush Franseria deltoidea	Pollens - Weeds and Garden Plants: Rabbit Bush, Ambrosia deltoidea	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Ragweed, False Franseria acanthicarpa	Pollens - Weeds and Garden Plants: Ragweed, False, Ambrosia acanthicarpa	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Ragweed, False Franseria ambrosioides	Pollens - Weeds and Garden Plants: Ragweed, False, Ambrosia ambrosioides	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Ragweed, False Mixed Franseria spp.	Pollens - Weeds and Garden Plants: Ragweed, False, Ambrosia (species to be specified)	The scientific and common names are ambiguous.
Pollens - Weeds and Garden Plants, Ragweed, Mixed Ambrosia spp.	Pollens - Weeds and Garden Plants: Ragweed, Ambrosia (species to be specified)	The scientific and common names are ambiguous.

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Animal Allergens: Gerbil Epithelia, *Meriones unguiculatus*

Animal Allergens: Goat Epithelia, *Capra hircus*

Animal Allergens: Hamster Epithelia, *Mesocricetus auratus*

Animal Allergens: Hog Epithelia, *Sus scrofa*

Animal Allergens: Horse Epithelia, *Equus caballus*

Animal Allergens: Mouse Epithelia, *Mus musculus*

Animal Allergens: Rabbit Epithelia, *Oryctolagus cuniculus*

Animal Allergens: Rat Epithelia, *Rattus norvegicus*

Food - Animal Products and Poultry Products: Lamb, *Ovis aries*

Food - Animal Products and Poultry Products: Pork, *Sus scrofa*

Food - Animal Products and Poultry Products: Turkey meat, *Meleagris gallopavo*

Food - Fish and Shellfish: Bass, Black, *Centropristis striata*

Food - Fish and Shellfish: Halibut, *Hippoglossus hippoglossus*

Food - Fish and Shellfish: Lobster, *Homarus americanus*

Food - Fish and Shellfish: Mackerel, *Scomber scombrus*

Food - Fish and Shellfish: Salmon, *Salmo salar*

Food - Plant Source: Almond, *Prunus dulcis*

Food - Plant Source: Apple, *Malus pumila*

Food - Plant Source: Apricot, *Prunus armeniaca*

Food - Plant Source: Barley, Whole Grain, *Hordeum vulgare*

Food - Plant Source: Bean, Lima, *Phaseolus lunatus*

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Food - Plant Source: Bean, Navy, Phaseolus vulgaris

Food - Plant Source: Bean, String Green, Phaseolus vulgaris

Food - Plant Source: Brazil Nut, Bertholletia excelsa

Food - Plant Source: Buckwheat, Fagopyrum esculentum

Food - Plant Source: Cacao bean, Theobroma cacao

Food - Plant Source: Carrot, Daucus carota

Food - Plant Source: Cashew nut, Anacardium occidentale

Food - Plant Source: Celery, Apium graveolens (or Apium graveolens var. dulce)

Food - Plant Source: Cinnamon, Cinnamomum verum

Food - Plant Source: Coconut, Cocos nucifera

Food - Plant Source: Coffee, Coffea arabica

Food - Plant Source: Corn, Zea mays

Food - Plant Source: Cranberry, Vaccinium macrocarpon

Food - Plant Source: Cucumber, Cucumis sativus

Food - Plant Source: Filbert, Corylus americana

Food - Plant Source: Garlic, Allium sativum

Food - Plant Source: Ginger, Zingiber officinale

Food - Plant Source: Hops, Humulus lupulus

Food - Plant Source: Lettuce, Lactuca sativa

Food - Plant Source: Mushroom, Agaricus campestris

Food - Plant Source: Oat, Avena sativa

Food - Plant Source: Olive, Green, Olea europaea

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Food - Plant Source: Pea, Green or English, *Pisum sativum*

Food - Plant Source: Peach, *Prunus persica*

Food - Plant Source: Peanut, *Arachis hypogaea*

Food - Plant Source: Pear, *Pyrus communis*

Food - Plant Source: Pepper, Black, *Piper nigrum*

Food - Plant Source: Pepper, Green, *Capsicum annuum*

Food - Plant Source: Pineapple, *Ananas comosus*

Food - Plant Source: Potato, Sweet, *Ipomoea batatas*

Food - Plant Source: Potato, White, *Solanum tuberosum*

Food - Plant Source: Raspberry, Red, *Rubus idaeus*

Food - Plant Source: Rice, *Oryza sativa*

Food - Plant Source: Rye, *Secale cereale*

Food - Plant Source: Soybean, *Glycine max*

Food - Plant Source: Spinach, *Spinacia oleracea*

Food - Plant Source: Walnut, Black, *Juglans nigra*

Food - Plant Source: Walnut, English, *Juglans regia*

Food - Plant Source: Watermelon, *Citrullus lanatus*

Food - Plant Source: Wheat, Whole, *Triticum aestivum*

Insects (Whole Body): Ant, Black Carpenter, *Camponotus pennsylvanicus*

Insects (Whole Body): Ant, Fire, *Solenopsis invicta*

Insects (Whole Body): Ant, Fire, *Solenopsis richteri*

Insects (Whole Body): Cockroach, American, *Periplaneta americana*

Insects (Whole Body): House Fly, *Musca domestica*

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Insects (Whole Body): Mosquito, *Aedes taeniorhynchus*

Molds, Rusts and Smuts: *Aspergillus flavus*

Molds, Rusts and Smuts: *Aspergillus fumigatus*

Molds, Rusts and Smuts: *Aspergillus nidulans*

Molds, Rusts and Smuts: *Aspergillus niger*

Molds, Rusts and Smuts: *Aureobasidium pullulans*

Molds, Rusts and Smuts: Bermuda Grass Smut, *Ustilago cynodontis*

Molds, Rusts and Smuts: *Bipolaris sorokiniana*

Molds, Rusts and Smuts: *Botrytis cinerea*

Molds, Rusts and Smuts: *Candida albicans*

Molds, Rusts and Smuts: *Chaetomium globosum*

Molds, Rusts and Smuts: *Cladosporium herbarum*

Molds, Rusts and Smuts: *Cladosporium sphaerospermum*

Molds, Rusts and Smuts: Corn Smut, *Ustilago maydis*

Molds, Rusts and Smuts: *Epicoccum nigrum*

Molds, Rusts and Smuts: *Epidermophyton floccosum*

Molds, Rusts and Smuts: *Fusarium solani*

Molds, Rusts and Smuts: *Geotrichum candidum*

Molds, Rusts and Smuts: *Gliocladium viride*

Molds, Rusts and Smuts: *Helminthosporium solani*

Molds, Rusts and Smuts: *Microsporum canis*

Molds, Rusts and Smuts: *Mucor circinelloides* f. *circinelloides*

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Molds, Rusts and Smuts: *Mucor circinelloides* f. *lusitanicus*

Molds, Rusts and Smuts: *Mucor plumbeus*

Molds, Rusts and Smuts: *Mycogone perniciosa*

Molds, Rusts and Smuts: *Neurospora intermedia*

Molds, Rusts and Smuts: *Nigrospora oryzae*

Molds, Rusts and Smuts: Oat Smut, *Ustilago avenae*

Molds, Rusts and Smuts: *Penicillium camemberti*

Molds, Rusts and Smuts: *Penicillium chrysogenum*

Molds, Rusts and Smuts: *Penicillium digitatum*

Molds, Rusts and Smuts: *Penicillium notatum*

Molds, Rusts and Smuts: *Penicillium roqueforti*

Molds, Rusts and Smuts: *Phoma betae*

Molds, Rusts and Smuts: *Rhizopus stolonifer*

Molds, Rusts and Smuts: *Rhodotorula mucilaginosa*

Molds, Rusts and Smuts: *Saccharomyces cerevisiae*

Molds, Rusts and Smuts: *Stemphylium solani*

Molds, Rusts and Smuts: *Trichoderma harzianum*

Molds, Rusts and Smuts: *Trichophyton mentagrophytes*

Molds, Rusts and Smuts: *Trichophyton rubrum*

Molds, Rusts and Smuts: *Trichothecium roseum*

Plants and Plant Parts: Gum, *Tragacanth*, *Astragalus gummifer*

Plants and Plant Parts: *Kapok*, *Ceiba pentandra*

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Pollens - Cultivated Farm Plants: Alfalfa, *Medicago sativa*

Pollens - Cultivated Farm Plants: Beet, Sugar, *Beta vulgaris*

Pollens - Cultivated Farm Plants: Corn, *Zea mays*

Pollens - Cultivated Farm Plants: Rye, *Secale cereale*

Pollens - Cultivated Farm Plants: Wheat, Cultivated, *Triticum aestivum*

Pollens - Flowers: Dandelion *Taraxacum officinale*

Pollens - Flowers: Sunflower, *Helianthus annuus*

Pollens - Grasses: Bahia Grass, *Paspalum notatum*

Pollens - Grasses: Bluegrass, Canada, *Poa compressa*

Pollens - Grasses: Brome, Smooth, *Bromus inermis*

Pollens - Grasses: Canarygrass, Reed, *Phalaris arundinacea*

Pollens - Grasses: Corn, Cultivated, *Zea mays*

Pollens - Grasses: Johnson Grass, *Sorghum halepense*

Pollens - Grasses: Oats, Common, Cultivated, *Avena sativa*

Pollens - Grasses: Rye, Cultivated, *Secale cereale*

Pollens - Grasses: Ryegrass, Italian, *Lolium multiflorum*

Pollens - Grasses: Saltgrass, *Distichlis spicata*

Pollens - Grasses: Velvetgrass, *Holcus lanatus*

Pollens - Grasses: Wheat, Cultivated, *Triticum aestivum*

Pollens - Trees: Alder, Red, *Alnus rubra*

Pollens - Trees: Alder, White, *Alnus rhombifolia*

Pollens - Trees: Ash, Arizona (Velvet), *Fraxinus velutina*

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Pollens - Trees: Ash, Green, Fraxinus pennsylvanica
Pollens - Trees: Ash, White, Fraxinus americana
Pollens - Trees: Aspen, Populus tremulooides
Pollens - Trees: Beech, American, Fagus grandifolia
Pollens - Trees: Beech, Hornbeam, Carpinus caroliniana
Pollens - Trees: Birch, Black-Sweet, Betula lenta
Pollens - Trees: Birch, River, Betula nigra
Pollens - Trees: Birch, Spring, Betula occidentalis
Pollens - Trees: Birch, White, Betula populifolia
Pollens - Trees: Box Elder, Acer negundo
Pollens - Trees: Cedar, Mountain, Juniperus ashei
Pollens - Trees: Cedar, Red, Juniperus virginiana
Pollens - Trees: Cedar, Salt (Tamarisk), Tamarix gallica
Pollens - Trees: Cottonwood, Black, Populus trichocarpa
Pollens - Trees: Cottonwood, Eastern, Populus deltoides
Pollens - Trees: Cypress, Bald, Taxodium distichum
Pollens - Trees: Elm, American, Ulmus americana
Pollens - Trees: Elm, Siberian, Ulmus pumila
Pollens - Trees: Eucalyptus, Blue Gum, Eucalyptus globulus
Pollens - Trees: Gum, Sweet, Liquidambar styraciflua
Pollens - Trees: Hackberry, Celtis occidentalis
Pollens - Trees: Hazelnut, American, Corylus americana
Pollens - Trees: Hickory, Shagbark, Carya ovata

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Pollens - Trees: Hickory, Shellbark, <i>Carya taciniosa</i>
Pollens - Trees: Juniper, Oneseed, <i>Juniperus monosperma</i>
Pollens - Trees: Juniper, Rocky Mountain, <i>Juniperus scopulorum</i>
Pollens - Trees: Juniper, Utah, <i>Juniperus osteosperma</i>
Pollens - Trees: Juniper, Western, <i>Juniperus occidentalis</i>
Pollens - Trees: Locust, Black, <i>Robinia pseudoacacia</i>
Pollens - Trees: Maple, Hard, <i>Acer saccharum</i>
Pollens - Trees: Maple, Red, <i>Acer rubrum</i>
Pollens - Trees: Maple, Soft, <i>Acer saccharinum</i>
Pollens - Trees: Melaleuca (Punk Tree), <i>Melaleuca quinquenervia</i>
Pollens - Trees: Mulberry, Paper, <i>Broussonetia papyrifera</i>
Pollens - Trees: Mulberry, Red, <i>Morus rubra</i>
Pollens - Trees: Mulberry, White, <i>Morus alba</i>
Pollens - Trees: Oak, Arizona (Gambel), <i>Quercus gambelii</i>
Pollens - Trees: Oak, Black, <i>Quercus velutina</i>
Pollens - Trees: Oak, Bur, <i>Quercus macrocarpa</i>
Pollens - Trees: Oak, California Live, <i>Quercus agrifolia</i>
Pollens - Trees: Oak, California White, <i>Quercus lobata</i>
Pollens - Trees: Oak, Post, <i>Quercus stellata</i>
Pollens - Trees: Oak, Red, <i>Quercus rubra</i>
Pollens - Trees: Oak, Scrub, <i>Quercus dumosa</i>
Pollens - Trees: Oak, Virginia Live, <i>Quercus virginiana</i>
Pollens - Trees: Oak, Western White <i>Quercus garryana</i>

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

- Pollens - Trees: Oak, White, Quercus alba
- Pollens - Trees: Olive, Olea europaea
- Pollens - Trees: Olive, Russian, Elaeagnus angustifolia
- Pollens - Trees: Pecan, Carya illinoensis
- Pollens - Trees: Pepper Tree, Brazilian, Schinus terebinthifolius
- Pollens - Trees: Pepper Tree, California, Schinus molle
- Pollens - Trees: Pine, Loblolly, Pinus taeda
- Pollens - Trees: Pine, Longleaf, Pinus palustris
- Pollens - Trees: Pine, Ponderosa, Pinus ponderosa
- Pollens - Trees: Pine, Slash, Pinus elliotii
- Pollens - Trees: Pine, Virginia Scrub, Pinus virginiana
- Pollens - Trees: Pine, White (Eastern), Pinus strobus
- Pollens - Trees: Pine, White (Western), Pinus monticola
- Pollens - Trees: Pine, Yellow, Pinus echinata
- Pollens - Trees: Poplar, White, Populus alba
- Pollens - Trees: Privet, Ligustrum vulgare
- Pollens - Trees: Sycamore, Western, Platanus racemosa
- Pollens - Trees: Walnut, Black, Juglans nigra
- Pollens - Trees: Walnut, English, Juglans regia
- Pollens - Trees: Wainut, Southern California Black, Juglans californica
- Pollens - Trees: Willow, Black, Salix nigra
- Pollens - Trees: Willow, Pussy, Salix discolor
- Pollens - Weeds and Garden Plants: Allscale, Atriplex polycarpa
- Pollens - Weeds and Garden Plants: Amaranth, Green, Amaranthus hybridus
- Pollens - Weeds and Garden Plants: Careless Weed, Amaranthus palmeri

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Pollens - Weeds and Garden Plants: Dock, Yellow (Curly Dock), *Rumex crispus*

Pollens - Weeds and Garden Plants: Dog Fennel, *Eupatorium capillifolium*

Pollens - Weeds and Garden Plants: Firebush, *Kochia scoparia*

Pollens - Weeds and Garden Plants: Goldenrod, *Solidago canadensis*

Pollens - Weeds and Garden Plants: Iodine Bush, *Allenrolfea occidentalis*

Pollens - Weeds and Garden Plants: Lamb's Quarters, *Chenopodium album*

Pollens - Weeds and Garden Plants: Lenscale Quailbrush, *Atriplex lentiformis*

Pollens - Weeds and Garden Plants: Marshelder, Narrowleaf, *Iva angustifolia*

Pollens - Weeds and Garden Plants: Mugwort, Common, *Artemisia vulgaris*

Pollens - Weeds and Garden Plants: Mugwort, Darkleaved, *Artemisia ludoviciana*

Pollens - Weeds and Garden Plants: Pigweed, Rough Redroot, *Amaranthus retroflexus*

Pollens - Weeds and Garden Plants: Pigweed, Spiny, *Amaranthus spinosus*

Pollens - Weeds and Garden Plants: Plantain, English, *Plantago lanceolata*

Pollens - Weeds and Garden Plants: Povertyweed, Small, *Iva axillaris*

Pollens - Weeds and Garden Plants: Ragweed, Desert, *Ambrosia dumosa*

Pollens - Weeds and Garden Plants: Ragweed, Giant (Tall), *Ambrosia trifida*

Pollens - Weeds and Garden Plants: Ragweed, Slender, *Ambrosia confertiflora*

Pollens - Weeds and Garden Plants: Ragweed, Southern, *Ambrosia bidentata*

Pollens - Weeds and Garden Plants: Ragweed, Western, *Ambrosia psilostachya*

Pollens - Weeds and Garden Plants: Russian Thistle, *Salsola kali*

Greer. Table 2: Licensed non-standardized allergenic extracts with correct identifiers

Pollens - Weeds and Garden Plants: Sagebrush, Coast, *Artemisia californica*

Pollens - Weeds and Garden Plants: Sagebrush, Common, *Artemisia tridentata*

Pollens - Weeds and Garden Plants: Sagebrush, Pasture, *Artemisia frigida*

Pollens - Weeds and Garden Plants: Saltbush, Annual, *Atriplex wrightii*

Pollens - Weeds and Garden Plants: Scale, All, *Atriplex polycarpa*

Pollens - Weeds and Garden Plants: Scale, Wing (Shad), *Atriplex canescens*

Pollens - Weeds and Garden Plants: Shadscale, *Atriplex confertifolia*

Pollens - Weeds and Garden Plants: Wormwood, Annual, *Artemisia annua*