

September 25, 2015

Express Mail

Robert D. Hughes
Allermed Laboratories, Inc.
Director of Operations
7203 Convoy Court
San Diego, California 92111

Dear Mr. Hughes:

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.allermed.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

cc:

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

Mark Hites
Greer Laboratories, Inc.
Authorizing Official
639 Nuway Circle, NE
Lenoir, North Carolina 28645

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

Current identifier	Recommended identifier	Explanation
Animal Allergens, Chicken Feathers Gallus sp.	Animal Allergens: Chicken feathers, Gallus gallus	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Dog Dander Canis spp.	Animal Allergens: Dog dander, Canis lupus familiaris	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Duck Feathers Anas platyrhynchos	Animal Allergens: Duck Feathers, Anas platyrhynchos	The scientific name is misspelled. The common name is correct.
Animal Allergens, Goat Dander Capra sp.	Animal Allergens: Goat Dander, Capra hircus	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Goose Feathers Chen spp.	Animal Allergens: Goose feathers, Chen (species to be specified)	The scientific name is ambiguous. The common name is correct.
Animal Allergens, Hamster Hair Cricetus sp.	Animal Allergens: Hamster Hair, Cricetus cricetus	The scientific name is ambiguous. The common name is correct.
Food - Animal Products and Poultry Products, Beef Bos sp	Food - Animal Products and Poultry Products: Beef, Bos taurus	The scientific name is ambiguous. The common name is correct.
Food - Animal Products and Poultry Products, Chicken Meat Gallus sp.	Food - Animal Products and Poultry Products: Chicken Meat, Gallus gallus	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.
Molds, Rusts and Smuts, Alternaria tenuis (alternata)	Molds, Rusts and Smuts: Alternaria alternata	Scientific name is obsolete.
Molds, Rusts and Smuts, Barley Smut, Covered Ustilago nigra	Molds, Rusts and Smuts: (common name to be specified), Ustilago avenae	Scientific name is obsolete. Common name is uncertain.
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, Cephalosporium spp.	Molds, Rusts and Smuts: Cephalosporium (species to be specified)	Scientific name is ambiguous.
Molds, Rusts and Smuts, Cladosporium cladosporioides	Molds, Rusts and Smuts: Cladosporium cladosporioides	Scientific name is misspelled.
Molds, Rusts and Smuts, Fusarium roseum	Molds, Rusts and Smuts: Gibberella pulicaris	Scientific name is obsolete.
Molds, Rusts and Smuts, Fusarium spp	Molds, Rusts and Smuts: Fusarium (species to be specified)	Scientific name is ambiguous.
Molds, Rusts and Smuts, Helminthosporium maydis	Molds, Rusts and Smuts: Bipolaris maydis	Scientific name is obsolete.
Molds, Rusts and Smuts, Helminthosporium sativum	Molds, Rusts and Smuts: Bipolaris sorokiniana	Scientific name is obsolete.
Molds, Rusts and Smuts, Johnson Grass Smut Sphacelotheca cruenta	Molds, Rusts and Smuts: (common name to be specified), Sporisorium cruentum	Scientific name is obsolete. Common name is uncertain.
Molds, Rusts and Smuts, Monilia sitophila	Molds, Rusts and Smuts: Chrysonilia sitophila	Scientific name is obsolete.
Molds, Rusts and Smuts, Pullularia pullulans	Molds, Rusts and Smuts: Aureobasidium pullulans	Scientific name is obsolete.
Molds, Rusts and Smuts, Rhizopus nigricans	Molds, Rusts and Smuts: Rhizopus stolonifer	Scientific name is obsolete.
Molds, Rusts and Smuts, Rhizopus oryzae	Molds, Rusts and Smuts: Rhizopus arrhizus	Scientific name is obsolete.
Molds, Rusts and Smuts, Stemphylium botryosum	Molds, Rusts and Smuts: Pleospora tarda	Scientific name is obsolete.

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

Molds, Rusts and Smuts, Wheat Smut, Loose <i>Ustilago tritici</i>	Molds, Rusts and Smuts: (common name to be specified), <i>Ustilago tritici</i>	Scientific name is correct. Common name is uncertain.
Molds, Rusts and Smuts, Wheat Stem Rust <i>Puccinia graminis tritici</i>	Molds, Rusts and Smuts: <i>Puccinia</i> (species to be specified)	Scientific name is ambiguous.
Plants and Plant Parts, Cotton Linters	Plants and Plant Parts: Cotton linters, <i>Gossypium</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Plants and Plant Parts, Cottonseed <i>Gossypium</i> spp.	Plants and Plant Parts: Cottonseed, <i>Gossypium</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Plants and Plant Parts, Flaxseed or Linseed <i>Linum usitatissimum</i>	Plants and Plant Parts: Flax, <i>Linum usitatissimum</i>	The scientific name is correct. The common name is ambiguous.
Plants and Plant Parts, Gum, Karaya or <i>Bassora Cochlospermum religiosum</i>	Plants and Plant Parts: Gum (Karaya or Bassora), <i>Silk-cotton Tree, Cochlospermum religiosum</i>	The scientific name is correct. The common name is ambiguous.
Plants and Plant Parts, Jute <i>Corchorus</i> sp.	Plants and Plant Parts: Jute, <i>Corchorus</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Plants and Plant Parts, Orris Root <i>Iris florentina</i>	Plants and Plant Parts: Orris root, <i>Iris germanica florentina</i>	The scientific name is obsolete. The common name is correct.
Plants and Plant Parts, Sisal <i>Agave sisalina</i>	Plants and Plant Parts: Sisal, <i>Agave sisalina</i>	The scientific name is misspelled. The common name is correct.
Plants and Plant Parts, Tobacco, Leaf	Plants and Plant Parts: Tobacco, Cultivated, Leaf, <i>Nicotiana tabacum</i>	The scientific name is absent. The common name is correct.
Pollens - Cultivated Farm Plants, Mustard, Field <i>Brassica campestris</i>	Pollens - Cultivated Farm Plants: Mustard, Field, <i>Brassica rapa</i>	The scientific name is obsolete. The common name is correct.
Pollens - Flowers, Sunflower <i>Helianthus</i> spp.	Pollens - Flowers: Sunflower, <i>Helianthus</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Grasses, Canarygrass, Small <i>Phalaris arundinaceae</i>	Pollens - Grasses: Canarygrass, Reed, <i>Phalaris arundinaceae</i>	The scientific name is misspelled. The common name is correct.
Pollens - Grasses, Koeler's Grass (Western Junegrass) <i>Koeleria cristata</i>	Pollens - Grasses: Koeler's Grass (Western Junegrass), <i>Koeleria pyramidata</i>	The scientific name is obsolete. The common name is correct.
Pollens - Grasses, Quack (Couch) Grass <i>Agropyron repens</i>	Pollens - Grasses: Quack (Couch) Grass, <i>Elymus repens</i>	The scientific name is obsolete. The common name is correct.
Pollens - Grasses, Ryegrass, Giant Wild <i>Elymus condensatus</i> (cinereus)	Pollens - Grasses: Ryegrass, Giant Wild, <i>Elymus condensatus</i>	The scientific name is obsolete. The common name is correct.
Pollens - Grasses, Wheatgrass, Western <i>Agropyron smithii</i>	Pollens - Grasses: Wheatgrass, Western, <i>Pascopyrum smithii</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Acacia spp.	Pollens - Trees: Acacia, <i>Acacia</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Alder, Tag-Smooth <i>Alnus rugosa</i>	Pollens - Trees: Alder, Tag-Smooth, <i>Alnus incana</i> ssp. <i>rugosa</i> .	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Beech, American <i>Fagus americana</i>	Pollens - Trees: Beech, American, <i>Fagus grandifolia americana</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Birch, Mix <i>Betula</i> spp.	Pollens - Trees: Birch, <i>Betula</i> (species to be specified)	The scientific and common names are ambiguous.
Pollens - Trees, Bottle Brush <i>Callistemon</i> spp.	Pollens - Trees: Bottle Brush, <i>Callistemon</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Cedar, Mountain <i>Juniperus sabinoides</i>	Pollens - Trees: Cedar, Mountain, <i>Juniperus ashei sabinoides</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Cottonwood <i>Populus</i> spp.	Pollens - Trees: Cottonwood, <i>Populus</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Cottonwood, Fremont <i>Populus fremonti</i>	Pollens - Trees: Cottonwood, Fremont, <i>Populus fremonti</i>	The scientific name is misspelled. The common name is correct.
Pollens - Trees, Cypress, Arizona <i>Cupressus arizonica</i>	Pollens - Trees: Cypress, Arizona, <i>Callitropsis arizonica</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Elm Mix <i>Ulmus</i> spp.	Pollens - Trees: Elm Mix, <i>Ulmus</i> (species to be specified)	The scientific and common names are ambiguous.

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

Pollens - Trees, Hickory <i>Carya</i> spp.	Pollens - Trees: Hickory, <i>Carya</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Maple <i>Acer</i> spp.	Pollens - Trees: Maple, <i>Acer</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Oak, California Black <i>Quercus kelloggii</i> -californica	Pollens - Trees: Oak, California Black, <i>Quercus kelloggii</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Oak, Mix <i>Quercus</i> spp.	Pollens - Trees: Oak, Mix, <i>Quercus</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Orange Blossom <i>Citrus</i> spp.	Pollens - Trees: Orange Blossom, <i>Citrus</i> (species to be specified)	The scientific name is ambiguous. The common name is correct.
Pollens - Trees, Palo Verde <i>Cercidium torreyana</i>	Pollens - Trees: Palo Verde, <i>Parkinsonia</i> (species to be specified)	The scientific name is obsolete and ambiguous. The common name is correct.
Pollens - Trees, Pine, Austrian <i>Pinus nigra</i>	Pollens - Trees: Pine, Austrian, <i>Pinus nigra</i>	The scientific name is correct. The common name is misspelled.
Pollens - Trees, Pine, Mix <i>Pinus</i> spp.	Pollens - Trees: (common name to be specified), <i>Pinus</i> (species to be specified)	The scientific and common names are ambiguous.
Pollens - Trees, Pine, Norfolk Island <i>Anacardium excelsa</i>	Pollens - Trees: (common name to be specified), <i>Araucaria</i> (species to be specified)	The scientific name is misspelled and obsolete. The common name and scientific names do not match.
Pollens - Trees, Poplar, Lombardy <i>Populus nigra italica</i>	Pollens - Trees: Poplar, Lombardy, <i>Populus nigra</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Sycamore, American (Eastern) <i>Platanus occidentalis</i>	Pollens - Trees: Sycamore, American (Eastern), <i>Platanus occidentalis</i>	The scientific name is misspelled. The common name is correct.
Pollens - Trees, Wax Myrtle, <i>Myrica cerifera</i>	Pollens - Trees: Wax Myrtle, <i>Morella cerifera</i>	The scientific name is obsolete. The common name is correct.
Pollens - Trees, Willow, Arroyo <i>Salix lasiolepis</i>	Pollens - Trees: Willow, Arroyo, <i>Salix lasiolepis</i>	The scientific name is misspelled. The common name is correct.
Pollens - Weeds and Garden Plants, <i>Amaranthus</i> , Mixed <i>Amaranthus</i> spp.	Pollens - Weeds and Garden Plants: <i>Amaranthus</i> , Mixed, <i>Amaranthus</i> (species to be specified)	The scientific and common names are ambiguous.
Pollens - Weeds and Garden Plants, Burro Brush <i>Hymenoclea salsola</i> (Greasebush)	Pollens - Weeds and Garden Plants: Burro Brush (<i>Greasebush</i>), <i>Ambrosia salsola</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Cocklebur <i>Xanthium commune</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, Hemp, Western Water <i>Achida tamariscina</i>	Pollens - Weeds and Garden Plants: Hemp, Western Water, <i>Amaranthus tuberculatus</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Marshelder, Burweed (Giant Poverty) <i>Iva xanthifolia</i>	Pollens - Weeds and Garden Plants: Marshelder, Burweed (<i>Giant Poverty</i>), <i>Cyclachaena xanthifolia</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Marshelder, True (Rough) <i>Iva ciliata</i>	Pollens - Weeds and Garden Plants: Marshelder, True (<i>Rough</i>), <i>Iva annua</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Rabbit Bush <i>Franseria deltoidea</i>	Pollens - Weeds and Garden Plants: Rabbit Bush, <i>Ambrosia deltoidea</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Ragweed, Canyon <i>Franseria ambrosioides</i>	Pollens - Weeds and Garden Plants: Ragweed, Canyon, <i>Ambrosia ambrosioides</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Ragweed, False <i>Franseria acanthicarpa</i>	Pollens - Weeds and Garden Plants: Ragweed, False, <i>Ambrosia acanthicarpa</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Ragweed, Mixed <i>Ambrosia</i> spp.	Pollens - Weeds and Garden Plants: Ragweed, <i>Ambrosia</i> (species to be specified)	The scientific and common names are ambiguous.
Pollens - Weeds and Garden Plants, Ragweed, Sandbur <i>Ambrosia bipinnatifida</i>	Pollens - Weeds and Garden Plants: Ragweed, Sandbur, <i>Ambrosia</i> (species to be specified)	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Ragweed, Slender <i>Franseria tenuifolia</i>	Pollens - Weeds and Garden Plants: Ragweed, Slender, <i>Ambrosia tenuifolia</i>	The scientific name is obsolete. The common name is correct.

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

Pollens - Weeds and Garden Plants, Sage, Desert, <i>Artemisia californica</i>	Pollens - Weeds and Garden Plants: Sage, Desert, <i>Artemisia californica</i>	The scientific name is misspelled. The common name is correct.
Pollens - Weeds and Garden Plants, Sage, Green, <i>Artemisia dracunculoides</i>	Pollens - Weeds and Garden Plants: Sage, Green, <i>Artemisia dracunculoides</i>	The scientific name is misspelled. The common name is correct.
Pollens - Weeds and Garden Plants, Sage, <i>Artemisia ludoviciana</i>	Pollens - Weeds and Garden Plants: Sage, <i>Artemisia ludoviciana</i>	The scientific name is correct. The common name is ambiguous.
Pollens - Weeds and Garden Plants, Sage, Mixed <i>Artemisia</i> spp.	Pollens - Weeds and Garden Plants: Sage, <i>Artemisia</i> (species to be specified)	The scientific and common names are ambiguous.
Pollens - Weeds and Garden Plants, Sage, Mixed <i>Artemisia tridentata</i>	Pollens - Weeds and Garden Plants: Sage, <i>Artemisia tridentata</i>	The scientific name is correct. The common name is ambiguous.
Pollens - Weeds and Garden Plants, Scale, Brewers <i>Atriplex lentiformis breweri</i>	Pollens - Weeds and Garden Plants: Scale, Brewers, <i>Atriplex lentiformis</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Scale, Silver (Fogweed) <i>Atriplex argentea expansa</i>	Pollens - Weeds and Garden Plants: Scale, Silver (Fogweed), <i>Atriplex argentea</i> var. <i>expansa</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Scale, Spear <i>Atriplex patula hastata</i>	Pollens - Weeds and Garden Plants: Scale, Spear, <i>Atriplex prostrata</i>	The scientific name is obsolete. The common name is correct.
Pollens - Weeds and Garden Plants, Sea Blite, Alkali <i>Suaeda fruticosa</i>	Pollens - Weeds and Garden Plants: Sea Blite, Alkali, <i>Suaeda nigra</i>	The scientific name is obsolete. The common name is correct.

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

Animal Allergens: Cattle dander, <i>Bos taurus</i>
Animal Allergens: Guinea Pig Hair, <i>Cavia porcellus</i>
Animal Allergens: Hog Dander, <i>Sus scrofa</i>
Animal Allergens: Horse Dander, <i>Equus caballus</i>
Animal Allergens: Mouse Hair, <i>Mus musculus</i>
Insects (Whole Body): Ant, Black, <i>Monomorium minimum</i>
Insects (Whole Body): Ant, Carpenter, <i>Camponotus pennsylvanicus</i>
Insects (Whole Body): Ant, Fire, <i>Solenopsis geminata</i>
Insects (Whole Body): Ant, Red, <i>Monomorium pharaonis</i>
Insects (Whole Body): Cockroach, American, <i>Periplaneta americana</i>
Molds, Rusts and Smuts: <i>Alternaria solani</i>
Molds, Rusts and Smuts: <i>Aspergillus clavatus</i>
Molds, Rusts and Smuts: <i>Aspergillus flavipes</i>
Molds, Rusts and Smuts: <i>Aspergillus fumigatus</i>
Molds, Rusts and Smuts: <i>Aspergillus glaucus</i>
Molds, Rusts and Smuts: <i>Aspergillus nidulans</i>
Molds, Rusts and Smuts: <i>Aspergillus niger</i>
Molds, Rusts and Smuts: <i>Aspergillus ochraceus</i>
Molds, Rusts and Smuts: <i>Aspergillus terreus</i>
Molds, Rusts and Smuts: <i>Aspergillus ustus</i>
Molds, Rusts and Smuts: Bermuda Grass Smut, <i>Ustilago cynodontis</i>
Molds, Rusts and Smuts: <i>Botrytis cinerea</i>

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

Molds, Rusts and Smuts: Brome Grass, Cheat, *Ustilago bullata*

Molds, Rusts and Smuts: *Candida albicans*

Molds, Rusts and Smuts: *Chaetomium globosum*

Molds, Rusts and Smuts: *Cladosporium herbarum*

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

Molds, Rusts and Smuts: *Curvularia inaequalis*

Molds, Rusts and Smuts: *Curvularia lunata*

Molds, Rusts and Smuts: *Epicoccum nigrum*

Molds, Rusts and Smuts: *Fusarium solani*

Molds, Rusts and Smuts: *Mucor plumbeus*

Molds, Rusts and Smuts: *Mucor racemosus*

Molds, Rusts and Smuts: *Neurospora crassa*

Molds, Rusts and Smuts: *Neurospora sitophila*

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

Molds, Rusts and Smuts: *Penicillium chrysogenum*

Molds, Rusts and Smuts: *Penicillium notatum*

Molds, Rusts and Smuts: *Phoma betae*

Molds, Rusts and Smuts: *Rhizopus arrhizus*

Molds, Rusts and Smuts: *Saccharomyces cerevisiae*

Molds, Rusts and Smuts: *Stemphylium solani*

Molds, Rusts and Smuts: *Trichophyton mentagrophytes*

Molds, Rusts and Smuts: *Trichophyton rubrum*

Molds, Rusts and Smuts: *Trichophyton tonsurans*

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

Molds, Rusts and Smuts: Wheat Rust, *Puccinia striiformis*

Molds, Rusts and Smuts: Wheat, Smut, *Tilletia controversa*

Plants and Plant Parts: Kapok, *Ceiba pentandra*

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: Hops, *Humulus lupulus*

Pollens - Cultivated Farm Plants: Mustard, Black, *Brassica nigra*

Pollens - Flowers: Dandelion *Taraxacum officinale*

Pollens - Grasses: Bahia Grass, *Paspalum notatum*

Pollens - Grasses: Bluegrass, Annual, *Poa annua*

Pollens - Grasses: Brome, Cheat, *Bromus secalinus*

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

Pollens - Grasses: Johnson Grass, *Sorghum halepense*

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

Pollens - Grasses: Saltgrass, *Distichlis spicata*

Pollens - Grasses: Velvetgrass, *Holcus lanatus*

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

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

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

Pollens - Trees: Ash, Green, *Fraxinus pennsylvanica*

Pollens - Trees: Ash, White, *Fraxinus americana*

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

Pollens - Trees: Aspen, <i>Populus tremulooides</i>
Pollens - Trees: Birch, Cherry, <i>Betula lenta</i>
Pollens - Trees: Birch, River, <i>Betula nigra</i>
Pollens - Trees: Birch, Spring, <i>Betula occidentalis</i>
Pollens - Trees: Birch, White, <i>Betula populifolia</i>
Pollens - Trees: Box Elder, <i>Acer negundo</i>
Pollens - Trees: Cedar, Red, <i>Juniperus virginiana</i>
Pollens - Trees: Cedar, Salt (Tamarisk), <i>Tamarix gallica</i>
Pollens - Trees: Cottonwood, Black, <i>Populus trichocarpa</i>
Pollens - Trees: Cottonwood, Common, <i>Populus deltoides</i>
Pollens - Trees: Cottonwood, Eastern, <i>Populus deltoides</i>
Pollens - Trees: Elm, American, <i>Ulmus americana</i>
Pollens - Trees: Elm, Fallblooming, <i>Ulmus parvifolia</i>
Pollens - Trees: Elm, Siberian, <i>Ulmus pumila</i>
Pollens - Trees: Eucalyptus, Blue Gum, <i>Eucalyptus globulus</i>
Pollens - Trees: Gum, Sweet, <i>Liquidambar styraciflua</i>
Pollens - Trees: Hackberry, <i>Celtis occidentalis</i>
Pollens - Trees: Hazelnut, American, <i>Corylus americana</i>
Pollens - Trees: Hickory, Shagbark, <i>Carya ovata</i>
Pollens - Trees: Hickory, White, <i>Carya tomentosa</i>
Pollens - Trees: Juniper, California, <i>Juniperus californica</i>
Pollens - Trees: Juniper, Rocky Mountain, <i>Juniperus scopulorum</i>
Pollens - Trees: Juniper, Utah, <i>Juniperus osteosperma</i>

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

Pollens - Trees: Juniper, Western, *Juniperus occidentalis*

Pollens - Trees: Linden, European, *Tilia cordata*

Pollens - Trees: Maple, Big-Leaf (Coast), *Acer macrophyllum*

Pollens - Trees: Oak, Black, *Quercus velutina*

Pollens - Trees: Oak, California Live, *Quercus agrifolia*

Pollens - Trees: Oak, California Scrub, *Quercus dumosa*

Pollens - Trees: Oak, Gambel, *Quercus gambelii*

Pollens - Trees: Oak, Red, *Quercus rubra*

Pollens - Trees: Oak, White, *Quercus alba*

Pollens - Trees: Olive, *Olea europaea*

Pollens - Trees: Olive, Russian, *Elaeagnus angustifolia*

Pollens - Trees: Palm, Date, *Phoenix dactylifera*

Pollens - Trees: Pecan, *Carya illinoensis*

Pollens - Trees: Pepper Tree, Brazilian, *Schinus terebinthifolius*

Pollens - Trees: Pepper Tree, California, *Schinus molle*

Pollens - Trees: Pine, Australian (Beefwood), *Casuarina equisetifolia*

Pollens - Trees: Pine, Western Yellow, *Pinus ponderosa*

Pollens - Trees: Pine, White (Eastern), *Pinus strobus*

Pollens - Trees: Pine, Yellow, *Pinus echinata*

Pollens - Trees: Poplar, *Populus deltoides*

Pollens - Trees: Poplar, White, *Populus alba*

Pollens - Trees: Privet, *Ligustrum vulgare*

Pollens - Trees: Redwood, *Sequoia sempervirens*

Pollens - Trees: Sycamore, Western, *Platanus racemosa*

Pollens - Trees: Tree of Heaven, *Ailanthus altissima*

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

Pollens - Trees: Walnut, English, Juglans regia
Pollens - Trees: Walnut, 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, Amaranthus retroflexus
Pollens - Weeds and Garden Plants: Bassia, Bassia hyssopifolia
Pollens - Weeds and Garden Plants: Burning Bush-Summer Cypress, Kochia scoparia
Pollens - Weeds and Garden Plants: Careless Weed, Amaranthus palmeri
Pollens - Weeds and Garden Plants: Dock, Yellow (Curly Dock), Rumex crispus
Pollens - Weeds and Garden Plants: Goldenrod, Solidago canadensis
Pollens - Weeds and Garden Plants: Greasewood, Sarcobatus vermiculatus
Pollens - Weeds and Garden Plants: Iodine Bush, Allenrolfea occidentalis
Pollens - Weeds and Garden Plants: Lamb's Quarters, Chenopodium album
Pollens - Weeds and Garden Plants: Mugwort, Common, Artemisia vulgaris
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, Silver, Dicoria canescens
Pollens - Weeds and Garden Plants: Ragweed, Southern, Ambrosia bidentata

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

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

Pollens - Weeds and Garden Plants: Russian Thistle, Salsola tragus

Pollens - Weeds and Garden Plants: Sage, Hog, Artemisia vulgaris

Pollens - Weeds and Garden Plants: Sage, Wormwood, Artemisia absinthium

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

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

Pollens - Weeds and Garden Plants: Scale, Bract, Atriplex serenana

Pollens - Weeds and Garden Plants: Scale, Lens, Atriplex lentiformis

Pollens - Weeds and Garden Plants: Scale, Red, Atriplex rosea

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

Pollens - Weeds and Garden Plants: Sedge, Carex barbarae

Pollens - Weeds and Garden Plants: Sheep Fat, Atriplex confertifolia

Pollens - Weeds and Garden Plants: Wingscale, Atriplex canescens