Express Mail

Jose A. Moreno Toscano President ALK-Abello, Inc. 1700 Royston Lane Round Rock, Texas 78664

Dear Mr. Toscano:

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.alk-abello.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(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

Page 4 –Mr. Toscano, ALK-Abello, Inc.

cc:

Andrew Ameye Vice President ALK-Abello, Inc. 35 Channel Drive Port Washington, New York 11050

Steve Haynes Authorizing Official ALK-Abello, Inc. 35 Channel Drive Port Washington, New York 11050

Current identifier

Animal Allergens, Duck Feathers Anus platyrhynchos Animal Allergens, Chicken Feathers Gallus sp. Animal Allergens, Dog Epithelium Canis familians Animal Allergens, Cattle Epithelium, Bos sp.

Animal Allergons, Goose Feathers Chen spp.

Animal Allergens, Guinea Pig Epithelia Cavis porcellus

Animal Allergens, Hamster Epithelium Cricetus sp.

Food - Animal Products and Poultry Products, Beef Bos sp

Food - Animal Products and Poultry Products, Chicken Meat Food - Animal Products and Poultry Products, Egg, White Gallus

Food - Animal Products and Poultry Products, Egg, Whole Gallus sp. Gallus:

Food - Animal Products and Poultry Products, Egg, Yalk

Food - Animal Products and Poultry Products, Veal Gallus

Food - Dairy Products, Lactalbumin alpha, Cow's Milk Food - Dairy Products, Casein, Cow's Milk

Food - Dairy Products, Milk, Whole Cow's Food - Dairy Products, Whey, Cow's Milk

Food - Fish and Shellfish, Clam Mya

Food - Fish and Shellfish, Clam Venus Mercearia spp

Food - Fish and Shellfish, Crab Xiphosurus sowerbyi Food - Fish and Shellfish, Codfish Gadus callarias

Food - Fish and Shellfish, Flounder Pleuronectes sp.

Food - Fish and Shellfish, Oyster Ostrea spp.

Food - Fish and Shellfish, Shrimp Crago sp.

Food - Fish and Shellfish, Shrimp Penaeus sp.

Food - Fish and Shellfish, Tuna Neothunnus sp.

Food - Plant Source, Almond Prunus amygdalus Food - Fish and Shellfish, Tuna Thunnus sp.

Food - Plant Source, Apricot Prunus sp.

Food - Plant Source, Banana Musa sapientum

Food - Plant Source, Broccoli Brassica botrytis (or oleracea Food - Plant Source, Bean, Lima Phaseolus limensis var. botrytis) Food - Plant Source, Cabbage Brassica capitata (or oleracea Food - Plant Source: Cabbage, Brassica oleracea var. capitata var. capitata

Food - Plant Source, Cauliflower Brassica oleracea (or oleracea var. botrytis)

Recommended identifier

Animal Allergens: Dog Epithelium, Canis lupus familiaris Animal Allergens: Duck Feathers, Anas platyrhynchos Animal Allergens: Chicken feathers, Gallus gallus Animal Allergens: Cattle epithelium , Bos taurus

Animal Allergens: Goose feathers, Chen (species to be specified)

Animal Allergens: Guinea Pig Epithelia, Cavia porcellus

Animal Allergens: Hamster Epithelium, Cricetus cricetus

Food - Animal Products and Poultry Products: Beef, Bos taurus

Food - Animal Products and Poultry Products: Chicken Meat, Gallus gallus

Food - Animal Products and Poultry Products: Egg, white, Gallus gallus

Food - Animal Products and Poultry Products: Egg, whole, Gallus gallus

Food - Animal Products and Poultry Products: Egg, yolk, , Gallus gallus

Food - Animal Products and Poultry Products: Veal, Bos taurus

Food - Dairy Products: Casein, Bos taurus

Food - Dairy Products: Lactalburnin alpha, Bos taurus

Food - Dairy Products: Whey, Bos taurus Food - Dairy Products: Milk, Bos taurus

Food - Fish and Shellfish: Clam, Mya (species to be specified)

Food - Fish and Shellfish: Clam Venus, Mercenaria (species to be specified)

Food - Fish and Shellfish: Cod, Atlantic, Gadus morhua

Food - Fish and Shellfish: Crab, Horseshoe, (genus and species to be specified)

Food - Fish and Shellfish: Flounder, Plauronectes (species to be specified)

Food - Fish and Shelffish: Oyster, Ostrea (species to be specified)

Food - Fish and Shellfish: Shrimp, Penaeus (species to be specified)

Food - Fish and Shellfish: Shrimp , Crangon (species to be specified)

Food - Fish and Shellfish: Tuna, Thunnus (species to be specified)

Food - Fish and Shellfish: Tuna, Thunnus (species to be specified) Food - Plant Source: Almond, Prunus dulcis

Food - Plant Source: Apricot, Prunus (species to be specified) Food - Plant Source: Banana, Musa (species to be specified)

Food - Plant Source: Broccoli, Brassica oleracea var. botrytis Food - Plant Source: Bean, Lima, Phaseolus lunatus

Food - Plant Source: Cauliflower, Brassica oleracea var. botrytis

Explanation

The scientific name is ambiguous. The common name is correct. The common name is correct. The scientific name is misspelled. The common name is correct, The scientific name is incorrect. The common name is correct, The scientific name is ambiguous.

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Food - Plant Source: Mustard seed, Brassica (species to be specified) Food - Plant Source: Pepper, Green (bell), (species to be specified) Insects (Whole Body): Mosquito, Culex (species to be specified) Molds, Rusts and Smuts: Chaetomium (species to be specified) Food - Plant Source: Squash, Zucchini, Italian, Cucurbita pepo Food - Plant Source: Cherry, Prunus (species to be specified) Molds, Rusts and Smuts: Fusarium (species to be specified) Wolds, Rusts and Smuts: Bipolaris (species to be specified) Food - Plant Source: Grape, Vitis (species to be specified) Molds, Rusts and Smuts: Cladosporium cladosporioides Food - Plant Source: Cinnamon, Cinnamomum verum Food - Plant Source: Tomato, (species to be specified) Molds, Rusts and Smuts: Barley Smut, Ustilago hordei Food - Plant Source: Strawberry, Fragaria X ananassa Food - Plant Source: Wheat grain, Triticum aestivum Food - Plant Source: Watermelon, Citrullus lanatus Molds, Rusts and Smuts: , Aspergillus amstelodami Wolds, Rusts and Smuts: Fusarium sporotrichioides Molds, Rusts and Smuts: Chaetomium globosum Food - Plant Source: Grapefruit, Citrus X paradis Food - Plant Source: Rye Grain, Secale cereale Molds, Rusts and Smuts: Trichothecium roseum Food - Plant Source: Pecan, Carya illinoinensis Food - Plant Source: Orange, Citrus X sinensis Molds, Rusts and Smuts: Sarocladium strictum Food - Plant Source: Corn, Sweet, Zea mays Food - Plant Source: Oat grain, Avena sativa Food - Plant Source: Vanilla, Vanilla planifolia Molds, Rusts and Smuts: Bipolaris sorokiniana Molds, Rusts and Smuts: Fusarium oxysporum Molds, Rusts and Smuts: Dendryphiella vinosa Molds, Rusts and Smuts: Aspergillus sydowii Food - Plant Source: Lemon, Citrus X limon Food - Plant Source: Soybean, Glycine max Molds, Rusts and Smuts: Alternaria alternata Molds, Rusts and Smuts: Gibberella pulicaris Molds, Rusts and Smuts: Epicoccum nigrum Molds, Rusts and Smuts: Gibberella fujikuroi nsects (Whole Body), Cockroach German Blatella germanica Insects (Whole Body); , Blattella germanica Molds, Rusts and Smuts: Bipolaris maydis Food - Plant Source: Onion, Allium cepa Molds, Rusts and Smuts, Helminthosporium interseminatum Food - Plant Source, Cinnamon Cinnamomum zeylanicum Molds, Rusts and Smuts, Barley Smut, Ustilago hoideu Molds, Rusts and Smuts, Bipolaris spp Molds, Rusts and Smuts, Cephalosponum acremonium Molds, Rusts and Smuts, Chaetomium sp. 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Plants and Plant Parts: Gum (Karaya or Bassora), Silk-cotton Tree, Cochlospermum religiosum Pollens - Grasses: Koeler's Grass (Western Junegrass), Koeleria pyramidata Plants and Plant Parts: Cotton linters, Gossypium (species to be specified) Pollens - Grasses: Brome, Corn Millet, (genus and species to be specified) Plants and Plant Parts: Cottonseed, Gossypium (species to be specified) Molds, Rusts and Smuts: (common name to be specified), Ustilago tritici Molds, Rusts and Smuts: Helminthosponum (species to be specified) Molds, Rusts and Smuts: Hormodendrum (species to be specified) Plants and Plant Parts: Pyrethrum, Chrysanthemum cinerariifolium Pollens - Cultivated Farm Plants: Clover, Red, Trifolium pratense Pollens - Flowers: Sunflower, Helianthus (species to be specified) Pollens - Cultivated Farm Plants, Clover, Sweet Meillotus alba Pollens - Cultivated Farm Plants: Clover, Sweet, Meillotus albus Pollens - Grasses: Saltgrass, Distichlis (species to be specified) Molds, Rusts and Smuts: Penicillium (species to be specified) Pollens - Grasses: Brome, Broncho/Ripgut, Bromus diandrus Pollens - Grasses: Brome, Soft Cheat, Bromus hordeaceus Rusts and Smuts: Phoma (species to be specified) Pollens - Grasses: Bamyard Grass, Echinochloa crus-galli Pollens - Grasses: Quack (Couch) Grass, Elymus repens Molds, Rusts and Smuts: Cladosporium cladosporioides Molds, Rusts and Smuts: Penicillium carminoviolaceum Pollens - Grasses: Gama Grass, Tripsacum dactyloides Pollens - Grasses: Ryegrass, Alkali, Leymus triticoides Plants and Plant Parts: Gum, Arabic, Acacia senegal Molds, Rusts and Smuts: Rhodotorula mucilaginosa Molds, Rusts and Smuts: Talaromyces funiculosus Molds, Rusts and Smuts; Helminthosporium solani Molds, Rusts and Smuts: Backusella lamprospora Plants and Plant Parts: Flax, Linum usitatissimum Molds, Rusts and Smuts: Penicillium camemberti Molds, Rusts and Smuts: Rhizopus microsporus Plants and Plant Parts: Orris root, Ins germanica Molds, Rusts and Smuts: Penicillium expansum Molds, Rusts and Smuts: Penicillium expansum Molds, Rusts and Smuts; Fonsecaea pedrosoi Molds, Rusts and Smuts: Talaromyces luteus Molds, Rusts and Smuts: Clonostachys rosea Molds, Rusts and Smuts: Talaromyces flavus Molds, Rusts and Smuts: Talaromyces ruber Molds, Rusts and Smuts: Rhizopus stolonifer Molds, Rusts and Smuts: Rhizopus arrhizus Molds, Rusts and Smuts, Wheat Smut, I.oose Ustilago tritici Pollens - Grasses, Quack (Couch) Grass Agropyron repens Molds, Rusts and Smuts, Hormodendrum (Cladosporium) Molds, Rusts and Smuts, Hormodendrum cladosponoides Pollens - Grasses, Brome Broncho-Ripgut Bromus rigidus Molds, Rusts and Smuts, Penicilium carmino-violaceum Pollens - Grasses, Barnyard Grass Echinochloa crusgalli Plants and Plant Parts, Pyrethrum Chrysanthemum spp. Pollens - Grasses, Koeler's Grass (Western Junegrass) Pollens - Grasses, Grama Grass, Tripsicum dactyloides Pollens - Cultivated Farm Plants, Clover, Red Trifolium Molds, Rusts and Smuts, Spondylocladium atrovirens Plants and Plant Parts, Gum, Acacia or Arabic Acacia Pollens - Grasses, Ryegrass, Alkali Elymus triticoides Pollens - Grasses, Saltgrass Distichlis sp. Pollens - Grasses, Brome, Soft Cheat Bromus mollis Plants and Plant Parts, Cottonseed Gossypium spp. Molds, Rusts and Smuts, Penicillium vermiculatum Plants and Plant Parts, Flaxseed or Linseed Linum Molds, Rusts and Smuts, Hormodendrum pedrosi Molds, Rusts and Smuts, Mucor rhizopodoformis Molds, Rusts and Smuts, Penicillium funiculosum Plants and Plant Parts, Gum, Karaya or Bassora Molds, Rusts and Smuts, Helminthosporium sp. Plants and Plant Parts, Orris Root Iris florentina Molds, Rusts and Smuts, Mucor lamprospora Molds, Rusts and Smuts, Penicillum glaucum Molds, Rusts and Smuts, Penicillium biforme Rusts and Smuts, Penicillium glaucus Rusts and Smuts, Penicillium roseum Molds, Rusts and Smuts, Penicillium luteum Rusts and Smuts, Penicillium rubrum Molds, Rusts and Smuts, Rhizopus nigricans Pollens - Flowers, Sunflower Helianthus spp. Rusts and Smuts, Rhodotorula rubra Rusts and Smuts, Penicillium spp. Molds, Rusts and Smuts, Mucor rouxii Plants and Plant Parts, Cotton Linters Pollens - Grasses, Brome, Corn Millet Rusts and Smuts, Phoma sp. Cochlospermum religiosum Koeleria cristata communis Molds, Molds, Molds, Molds,

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Pollens - Weeds and Garden Plants: (common name to be specified), Baccharis (species to be specified) Pollens - Weeds and Garden Plants: Beach Sandbur, Ambrosia chamissonis Pollens - Trees; Alder, Mountain (Tag-Slender), Alnus incana ssp. tenuifolia, Pollens - Trees: Cottonwood, Western, Populus deltoides ssp. Monilifera Pollens - Trees: Sycamore, American (Eastern), Platanus occidentalis Pollens - Trees: Pine, Australian, Casuarina (species to be specified) Pollens - Trees: Hazelnut, California, Corylus comuta ssp. californica Pollens - Trees: Eucalyptus, Eucalyptus (species to be specified) Pollens - Trees: Walnut, Hinds' Californía Black, Juglans hindsii Pollens - Trees: Cottonwood, Populus (species to be specified) Pollens - Trees: Groundsel, Baccharis (species to be specified) Pollens - Trees: Alder, Tag-Smooth, Ainus incana ssp. rugosa Pollens - Trees: Maple, Acer (species to be specified)
Pollens - Trees: Melaleuca blossom, Melaleuca leucadendra Pollens - Trees: Cypress, Monterey, Callitropsis macrocarpa Pollens - Trees: Mesquite, Prosopis (species to be specified) Pollens - Trees: Hackberry, Celtis (species to be specified) Pollens - Trees: Privet, Ligustrum (species to be specified) Pollens - Grasses: Sudan Grass, Sorghum X drummondii Pollens - Grasses: Sudan Grass, Sorghum X drummondii Pollens - Grasses: Sudan Grass, Sorghum X drummondi Pollens - Trees: Cottonwood, Fremont, Populus fremontii Pollens - Trees: Cottonwood, Arizona, Populus fremontii Pollens - Trees: Hickory, Carya (species to be specified) Pollens - Trees: Cypress, Arizona, Callitropsis arizonica Pollens - Trees; Ash, Fraxinus (species to be specified) Pollens - Trees: Palm, Queen, Syagrus romanzoffans Pollens - Trees: Planetree, Oriental, Platanus orientalis Pollens - Trees: Alder, Alnus (species to be specified) Pollens - Trees: Melaleuca, Melaleuca leucadendra Pollens - Trees: Cedar, Mountain, Juniperus ashei Pollens - Trees: Hickory, White, Carya tomentosa Pollens - Trees: Poplar, Lombardy, Populus nigra Pollens - Trees: Ash, Oregon, Fraxinus latifolia Pollens - Trees: Bayberry, Morella cerifera Pollens - Trees: Birch, River, Betula nigra Polions - Troes, Cypress, Monterey Cupressus macrocarpa Pollens - Grasses, Sudan Grass Andropogon sudanense Pollens - Trees, Sycamore, American (Eastern) Platanus Pollens - Trees, Cottonwood, Western Populus sargentii Pollens - Trees, Cottonwood, Fremont Populus fremonti Pollens - Trees, Sycamore, Western Platanus orientalis Pollens - Trees, Walnut, Hind's California Black Juglans Pollens - Trees, Cedar, Mountain Juniperus sabinoides Pollens - Trees, Cottonwood, Arizona Populus fremonti ollens - Trees, Cypress, Arizona Cupressus arizonica Pollens - Trees, Hazelnut, California Corylus californica Pollens - Trees, Poplar, Lombardy Populus nigra italica Pollens - Weeds and Gardon Plants, Beach Sandbur Pollens - Trees, Alder, Mountain (Tag-Slender) Alnus Pollens - Trees, Melaleuca Melaleuca leucadendrom Pollens - Trees, Willow Salix spp. Pollens - Weeds and Garden Plants, Baccharis spp. Pollens - Trees, Metaleuca Leucadendron Blossom Pollens - Grasses, Sudan Grass Sorghum vulgare Pollens - Grasses, Sudan Grass Sorghum vulgare ollens - Trees, Alder, Tag-Smooth Alnus rugosa تا Pollens - Trees, Ash, Oregon Fraxinus oregona Pollens - Troes, Pine, Australian Casuarina spp. Pollens - Trees, Palm, Queen Cocos plumosa Pollens - Trees, Hickory, White Carya alba Pollens - Trees, Cottonwood Populus spp. Pollens - Trees, Eucalyptus spp. Pollens - Trees, Groundsel, Baccharis sp. Pollens - Trees, Bayberry Myrica cerifera Pollens - Trees, Birch, Red Betula rubra Pollens - Trees, Mesquite Prosopis spp. Pollens - Trees, Hackberry Celtis spp. Pollens - Trees, Privet Ligustrum spp. Pollens - Trees, Ash Fraxinus spp. Pollens - Trees, Hickory Carya spp Pollens - Trees, Aider Alnus spp. Pollens - Trees, Maple Acer spp. ranseria chamissonis tenofolia/incana

occidentallis

Pollens - Weeds and Garden Plants: Bitterdock, Rumex obtusifolius Pollens - Weeds and Garden Plants, Cocklebur Xanthium Pollons - Weeds and Garden Plants, Bitterdock, Rumex

Pollens - Weeds and Garden Plants, Hemp, Western Water Pollens - Weeds and Garden Plants, Marshelder, Burweed Pollens - Weeds and Garden Plants, Cocklebur, Mixed Xanthium spp.

(Rough) Iva ciliata Pollens - Weeds and Garden Plants, Mugwort Artemisia spp. Pollens - Weeds and Garden Plants, Marshelder, True

(Giant Poverty) Iva xanthifolia

Pollens - Woods and Garden Plants, Mugwort, California Pollens - Weeds and Garden Plants, Nettle Urtica sp Artemesia heterophy

Pollens - Woeds and Garden Plants, Perietaria, Parietaria

Pollens - Weeds and Garden Plants, Pickleweed Salicomia

Pollens - Weeds and Garden Plants, Ragweed, False Franseria acanthicarpa

Pollens - Weeds and Garden Plants, Sagebrush, Prairie Artemisia gnaphalodes Pollens - Weeds and Garden Plants, Scale, Spear Atriplex patula hastata Pollens - Weeds and Garden Plants, Ragweed, Slender

Pollens - Weeds and Garden Plants: Mugwort, Artemisia (species to be specified) Pollens - Weeds and Garden Plants: Marshelder, True (Rough), Iva annua

Pollens - Weeds and Garden Plants: Marshelder, Burweed (Giant Poverty), Cyclachaena xanthiifolia

Pollens - Weeds and Garden Plants: Hemp, Western Water, Amaranthus tuberculatus Pollens - Weeds and Garden Plants: Cocklebur, Xanthium (species to be specified)

Pollens - Weeds and Garden Plants: Cocklebur, Xanthium strumarium

Pollons - Weeds and Garden Plants: Nettle, Urtica (species to be specified)

Pollens - Weeds and Garden Plants: Mugwort, California, Artemisia douglasiana

Pollens - Weeds and Garden Plants; Parietaria, Parietaria judaica

Pollens - Weeds and Garden Plants: Pickleweed, Sarcocomia perennis

Pollens - Weeds and Garden Plants: Ragweed, Slender, Ambrosia tenuifolia

Pollens - Weeds and Garden Plants: Ragweed, False, Ambrosia acanthicarpa

Pollens - Weeds and Garden Plants: Sagebrush, Prairie, Artemisia Iudoviciana ssp. ludoviciana

Pollens - Weeds and Garden Plants: Scale, Spear, Atriplex prostrata

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Animal Allergens: Gerbil Epithelia, Meriones unguiculatus

Animal Allergens: Goat Epithelia, Capra hircus

Animal Allergens: Hog Epithelia, Sus scrofa

Animal Allergens: Horse Dander, Equus caballus

Animal Allergens: House 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: Halibut, Hippoglossus hippoglossus

Food - Fish and Shellfish: Lobster, Homarus americanus

Food - Fish and Shellfish: Salmon, Salmo salar

Food - Plant Source: Apple, Malus pumila

Food - Plant Source: Asparagus, Asparagus officinalis

Food - Plant Source: Avocado, Persea americana

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

Food - Plant Source: Bean, Navy, Phaseolus vulgaris

Food - Plant Source: Bean, Pinto, Phaseolus vulgaris

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

Food - Plant Source: Beet, Beta vulgaris

Food - Plant Source: Brazil Nut, Bertholletia excelsa

Food - Plant Source: Buckwheat, Fagopyrum esculentum

Food - Plant Source: Cantaloupe, Cucumis melo

Food - Plant Source: Carrot, Daucus carota

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

Food - Plant Source: Cocoa Bean, Theobroma cacao

Food - Plant Source: Coconut, Cocos nucifera

Food - Plant Source: Coffee, Coffea arabica

Food - Plant Source: Cucumber, Cucumis sativus

Food - Plant Source: Garlic, Allium sativum

Food - Plant Source: Ginger, Zingiber officinale

Food - Plant Source: Honeydew melon, Cucumis melo

Food - Plant Source: Lettuce, Lactuca sativa

Food - Plant Source: Mushroom, Agaricus campestris

Food - Plant Source: Olive, Green, Olea europaea

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-White, Piper nigrum

Food - Plant Source: Pineapple, Ananas comosus

Food - Plant Source: Pistachio Nut, Pistacia vera

Food - Plant Source: Plum, Prunus domestica

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: Sesame seed, Sesamum indicum

Food - Plant Source: Spinach, Spinacia oleracea

Food - Plant Source: Tea, Camellia sinensis

Food - Plant Source: Turnip, Brassica rapa

Food - Plant Source: Walnut, English, Juglans regia

Food - Plant Source: Yeast, Baker's, Saccharomyces cerevisiae

Food - Plant Source: Yeast, Brewer's, Saccharomyces cerevisiae

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

Insects (Whole Body): Bee, Honey, Apis mellifera

nsects (Whole Body): Cockroach, American, Periplaneta americana

Molds, Rusts and Smuts: Alternaria solani

Molds, Rusts and Smuts: Aspergillus clavatus

Molds, Rusts and Smuts: Aspergillus flavipes

Molds, Rusts and Smuts: Aspergillus fumigatus

Molds, Rusts and Smuts: Aspergillus nidulans

Molds, Rusts and Smuts: Aspergillus ochraceus Molds, Rusts and Smuts: Aspergillus niger

Molds, Rusts and Smuts: Aspergillus repens Molds, Rusts and Smuts: Aspergillus oryzae

Molds, Rusts and Smuts: Aspergillus restrictus

Molds, Rusts and Smuts: Aspergillus terreus Molds, Rusts and Smuts: Aspergillus ustus Molds, Rusts and Smuts: Aspergillus versicolor

Molds, Rusts and Smuts: Aureobasidium pullulans

Molds, Rusts and Smuts: Botrytis cinerea

Molds, Rusts and Smuts: Chaetomium globosum Molds, Rusts and Smuts: Candida albicans

Molds, Rusts and Smuts: Chaetomium indicum

Molds, Rusts and Smuts: Cladosporium sphaerospermum

Molds, Rusts and Smuts: Corn Smut, Ustilago maydis

Molds, Rusts and Smuts: Curvularia lunata

Rusts and Smuts: Curvularia spicifera Molds,

Rusts and Smuts: Fusarium oxysporum Molds,

Rusts and Smuts: Fusarium solani Molds,

Molds, Rusts and Smuts: Mucor circinelloides

Molds, Rusts and Smuts: Mucor mucedo

Molds, Rusts and Smuts: Mucor plumbeus

Rusts and Smuts: Mucor racemosus Molds,

Rusts and Smuts: Neurospora intermedia Molds,

Molds, Rusts and Smuts: Nigrospora sphaerica

Molds, Rusts and Smuts: Oat Smut, Ustilago avenae Molds, Rusts and Smuts: Penicillium atramentosum

Molds, Rusts and Smuts: Penicillium camemberti

Molds, Rusts and Smuts: Penicillium chrysogenum

Molds, Rusts and Smuts: Penicillium digitatum

Molds, Rusts and Smuts: Penicillium expansum

Molds, Rusts and Smuts: Penicillium intricatum

Molds, Rusts and Smuts: Penicillium janthinellum Molds, Rusts and Smuts: Penicillium italicum

Molds, Rusts and Smuts: Penicillium notatum

Molds, Rusts and Smuts: Penicillium oxalicum

Molds, Rusts and Smuts: Penicillium roqueforti

Molds, Rusts and Smuts: Penicillium roseopurpureum

Molds, Rusts and Smuts: Phoma betae

Molds, Rusts and Smuts: Phoma destructiva

Molds, Rusts and Smuts: Phoma herbarum

Molds, Rusts and Smuts: Rhizopus arrhizus Molds, Rusts and Smuts: Phoma hibernica

Molds, Rusts and Smuts: Saccharomyces cerevisiae

Molds, Rusts and Smuts: Stemphylium sarciniforme

Molds, Rusts and Smuts: Trichoderma viride

Molds, Rusts and Smuts: Trichophyton mentagrophytes

Plants and Plant Parts: Gum, Tragacanth, Astragalus gummifer

Plants and Plant Parts: Kapok, Ceiba pentandra

Pollens - Cultivated Farm Plants: Clover, White, Trifolium repens Pollens - Cultivated Farm Plants: Alfalfa, Medicago sativa

Pollens - Flowers: Dandelion Taraxacum officinale

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

Pollens - Cultivated Farm Plants: Corn, Zea mays

Pollens - Grasses: Bahia Grass, Paspalum notatum Pollens - Flowers: Sunflower, Helianthus annuus

Pollens - Grasses: Bluegrass, Annual, Poa annua

Pollens - Grasses: Bluegrass, Canada, Poa compressa

Pollens - Grasses: Brome, California, Bromus carinatus

Pollens - Grasses: Brome, Cheat, Bromus secalinus

Pollens - Grasses: Brome, Smooth, Bromus inermis

Pollens - Grasses: Canarygrass, Phalaris canariensis

Pollens - Grasses: Canarygrass, Reed, Phalaris arundinacea

Pollens - Grasses: Canarygrass, Small, Phalaris minor

Poliens - Grasses: Johnson Grass, Sorghum halepense

Pollens - Grasses: Oat, Wild, Avena fatua

Pollens - Grasses: Ryegrass, Italian, Lolium multiflorum

Pollens - Grasses: Saltgrass, Distichlis spicata

Pollens - Grasses: Velvetgrass, Holcus lanatus

Pollens - Grasses: Wheat, Cultivated, Triticum aestivum

Pollens - Trees: Acacia, Acacia longifolia

Pollens - Trees: Acacia, Bailey's, Acacia baileyana

Pollens - Trees: Alder, Red, Alnus rubra

Pollens - Trees: Alder, White, Alnus rhombifolia

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

Pollens - Trees: Ash, Black, Fraxinus nigra

Pollens - Trees: Ash, Green, Fraxinus pennsylvanica

Pollens - Trees: Ash, White, Fraxinus americana

Pollens - Trees: Aspen, Populus tremuloides

Pollens - Trees: Beech, American, Fagus grandifolia

Pollens - Trees: Birch, Black-Sweet, Betula lenta

Pollens - Trees: Birch, River, Betula nigra

Pollens - Trees: Birch, White, Betula populifolia

Pollens - Trees: Box Elder, Acer negundo

Pollens - Trees: Cedar, Red, Juniperus virginiana

Pollens - Trees: Cedar, Salt, Tamarix gallica

Pollens - Trees: Cottonwood, Black, Populus trichocarpa

Pollens - Trees: Cottonwood, Common, Populus deltoides

Pollens - Trees: Cottonwood, Eastern, Populus deltoides

Pollens - Trees: Cypress, Bald, Taxodium distichum

Pollens - Trees: Cypress, Italian, Cupressus sempervirens

Pollens - Trees: Elm, American, Ulmus americana

Pollens - Trees: Elm, Cedar, Ulmus crassifolia

Pollens - Trees: Elm, Chinese, Ulmus parvifolia

Pollens - Trees: Elm, Siberian, Ulmus pumila

Pollens - Trees: Eucalyptus, Blue Gum, Eucalyptus globulus

Pollens - Trees: Greasewood, Sarcobatus vermiculatus

Pollens - Trees: Gum, Sweet, Liquidambar styraciflua

Pollens - Trees: Hackberry, Celtis occidentalis

Pollens - Trees: Hazelnut, American, Corylus americana

Pollens - Trees: Hickory, Pignut, Carya glabra

Pollens - Trees: Hickory, Shagbark, Carya ovata

Pollens - Trees: Hickory, Shellbark, Carya laciniosa

Pollens - Trees: Hickory, White, Carya tomentosa

Pollens - Trees: Hornbeam, Ostrya virginiana

Pollens - Trees: Juniper, Western, Juniperus occidentalis

Pollens - Trees: Linden (Basswood) Tilia americana Pollens - Trees: Locust, Black, Robinia pseudoacacia

Pollens - Trees: Maple, Red, Acer rubrum

Pollens - Trees: Maple, Sugar, Acer saccharinum

Pollens - Trees: Mesquite, Prosopis juliflora

Pollens - Trees: Mulberry, Red, Morus rubra Pollens - Trees: Mulberry, White, Morus alba

Pollens - Trees: Oak, California Live, Quercus agrifolia

Pollens - Trees: Oak, Coast Live, Quercus agrifolia

Pollens - Trees: Oak, Odast Live, Quercus agri Pollens - Trees: Oak, Pin, Quercus palustris

Pollens - Trees: Oak, Red, Quercus rubra

Pollens - Trees: Oak, Scrub, Quercus dumosa Pollens - Trees: Oak, Valley, Quercus lobata

rollens - Trees: Oak, Valley, Quercus lobata Pollens - Trees: Oak, Virginia Live, Quercus virginiana

Pollens - Trees: Oak, White, Quercus alba

Pollens - Trees: Olive, Olea europaea

Pollens - Trees: Pecan, Carya illinoinensis

Pollens - Trees: Pepper Tree, Brazilian, Schinus terebinthifolius

Pollens - Trees: Pepper Tree, California, Schinus molle

Pollens - Trees: Pine, Red, Pinus resinosa

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

Pollens - Trees: Pine, Yellow, Pinus echinata

Pollens - Trees: Planetree, London, Platanus acerifolia

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

Pollens - Trees: Walnut, Black, Juglans nigra

Pollens - Trees. wantut, black, Jugians nigra Pollens - Trees: Walnut, English, Jugians regia

Pollens - Trees: Wahnt, Southern California Black, Juglans californica

Pollens - Trees: Willow, Black, Salix nigra

Pollens - Trees: Willow, Pussy, Salix discolor

Pollens - Weeds and Garden Plants: Alfalfa, Medicago sativa

Pollens - Weeds and Garden Plants: Allscale, Atriplex polycarpa

Pollens - Weeds and Garden Plants: Bassia, Bassia hyssopifolia

Pollens - Weeds and Garden Plants: Careless Weed, Amaranthus palmeri

Pollens - Weeds and Garden Plants: Cattail, Typha latifolia

Pollens - Weeds and Garden Plants: Cocklebur, Xanthium strumarium

Pollens - Weeds and Garden Plants: Cocklebur, Spiny, Xanthium spinosum

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: Goldenrod, Solidago canadensis

Pollens - Weeds and Garden Plants: Hemp, Cannabis sativa

- Pollens Weeds and Garden Plants: Iodine Bush, Allenrolfea occidentalis
- Pollens Weeds and Garden Plants: Kochia (Mexican Firebush) Kochia scoparia
- 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 Iudoviciana
- 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: Ragweed, Giant (Tall), Ambrosia trifida
- 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
- Pollens Weeds and Garden Plants: Sagebrush, Artemisia annua
- Pollens Weeds and Garden Plants: Sagebrush, Coast, Artemisia californica
- Pollens Weeds and Garden Plants: Sagebrush, Common, Artemisia tridentata
- Pollens Weeds and Garden Plants: Sagebrush, Mugwort, Artemisia vulgaris
- Pollens Weeds and Garden Plants: Sagebrush, Pasture, Artemisia frigida
- Pollens Weeds and Garden Plants: Sagebrush, Prairie, Artemisia Iudoviciana
- Pollens Weeds and Garden Plants: Sagebrush, White (Prairie), Artemisia Iudoviciana
- Pollens Weeds and Garden Plants: Saltbush, Annual, Atriplex wrightii

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: Sheep Sorrel, Rumex acetosella

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