

**55714-4433-0**  
**HAY FEVER**  
**National Drug Code Directory**

The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.

**55714-4433-0 Hay Fever**

<i>Labeler Name</i>	Newton Laboratories, Inc.	Name of Company corresponding to the labeler code segment of the ProductNDC.
<i>NDC Package Code</i>	55714-4433-0	The labeler code, product code, and package code segments of the National Drug Code number, separated by hyphens. Asterisks are no longer used or included within the product and package code segments to indicate certain configurations of the NDC.
<i>Proprietary Name</i>	Hay Fever	Also known as the trade name. It is the name of the product chosen by the labeler.
<i>11 Digit NDC Code</i>	55714-4433-00	It should be noted that many NDCs are displayed on drug packaging in a 10-digit format. Proper billing of an NDC requires an 11-digit number in a 5-4-2 format. Converting NDCs from a 10-digit to 11-digit format requires a strategically placed zero, dependent upon the 10-digit format.
<i>Product NDC</i>	55714-4433	The labeler code and product code segments of the National Drug Code number, separated by a hyphen. Asterisks are no longer used or included within the product code segment to indicate certain configurations of the NDC.
<i>Product Type Name</i>	HUMAN PRESCRIPTION DRUG	Indicates the type of product, such as Human Prescription Drug or Human OTC Drug. This data element corresponds to the "Document Type" of the SPL submission for the listing. The complete list of codes and translations can be found at <a href="http://www.fda.gov/edrls">www.fda.gov/edrls</a> under Structured Product Labeling Resources.
<i>Non Proprietary Name</i>	Zerophyllum Asphodeloides, Alfalfa, Avena Sativa Pollen, Cynosurus Cristatus Pollen, Echinochloa Crus-galli Pollen, Poa Pratensis Pollen, Anthoxanthum Odoratum Pollen, Agrostis Gigantea Pollen, Bromus Secalinus Pollen, Alopecurus Pratensis Pollen, Phleum Pratense Pollen, Festuca Pratensis Pollen, Holcus Lanatus Pollen, Lolium Perenne Pollen, Fagus Sylvatica Pollen, Betula Pendula Pollen, Quercus Alba Pollen, Fraxinus Excelsior Pollen, Corylus Americana Pollen, Populus Nigra Pollen	Sometimes called the generic name, this is usually the active ingredient(s) of the product.
<i>Package Description</i>	7 g in 1 BOTTLE, GLASS (55714-4433-0)	A description of the size and type of packaging in sentence form. Multilevel packages will have the descriptions concatenated together. For example: 4 BOTTLES in 1 CARTON/100 TABLETS in 1 BOTTLE.

<i>Marketing Category Name</i>	UNAPPROVED HOMEOPATHIC	Product types are broken down into several potential Marketing Categories, such as NDA/ANDA/BLA, OTC Monograph, or Unapproved Drug. One and only one Marketing Category may be chosen for a product, not all marketing categories are available to all product types. Currently, only final marketed product categories are included. The complete list of codes and translations can be found at <a href="http://www.fda.gov/edrls">www.fda.gov/edrls</a> under Structured Product Labeling Resources.
<i>Product Marketing Start Date</i>	20110601	This is the date that the labeler indicates was the start of its marketing of the drug product.
<i>Dosage Form Name</i>	PELLET	The translation of the DosageForm Code submitted by the firm. The complete list of codes and translations can be found <a href="http://www.fda.gov/edrls">www.fda.gov/edrls</a> under Structured Product Labeling Resources.
<i>Route Name</i>	ORAL	The translation of the Route Code submitted by the firm, indicating route of administration. The complete list of codes and translations can be found at <a href="http://www.fda.gov/edrls">www.fda.gov/edrls</a> under Structured Product Labeling Resources.

<i>Substance Name</i>	XEROPHYLLUM ASPHODELOIDES; ALFALFA; AVENA SATIVA POLLEN; CYNOSURUS CRISTATUS POLLEN; ECHINOCHLOA CRUS- GALLI POLLEN; POA PRATENSIS POLLEN; ANTHOXANTHUM ODORATUM POLLEN; AGROSTIS GIGANTEA POLLEN; BROMUS SECALINUS POLLEN; ALOPECURUS PRATENSIS POLLEN; PHLEUM PRATENSE POLLEN; FESTUCA PRATENSIS POLLEN; HOLCUS LANATUS POLLEN; LOLIUM PERENNE POLLEN; FAGUS SYLVATICA POLLEN; BETULA PENDULA POLLEN; QUERCUS ALBA POLLEN; FRAXINUS EXCELSIOR POLLEN; CORYLUS AMERICANA POLLEN; POPULUS NIGRA POLLEN; PLATANUS ORIENTALIS POLLEN; ULMUS GLABRA POLLEN; SALIX ALBA POLLEN; NARCISSUS PSEUDONARCISSUS; ROSA CANINA FLOWER; LILIMUM CANDIDUM FLOWER; PRIMULA VULGARIS; DIANTHUS CARYOPHYLLUS FLOWER; ULEX EUROPAEUS FLOWER; CYTISUS SCOPARIUS POLLEN; CALLUNA VULGARIS POLLEN; CRATAEGUS MONOGYNA POLLEN; ACONITUM NAPELLUS; ARUNDO PLINIANA ROOT; DYSPHANIA AMBROSIOIDES; HELIANTHEMUM CANADENSE; DROsera ROTUNDIFOLIA; SOLANUM DULCAMARA TOP; LEDUM PALUSTRE TWIG; ONOSMODIUM VIRGINIANUM WHOLE; POPULUS TREMULOIDES LEAF; POPULUS TREMULOIDES BARK;	This is the active ingredient list. Each ingredient name is the preferred term of the UNII code submitted.
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	PULSATILLA VULGARIS; SANGUINARIA CANADENSIS ROOT; DATURA STRAMONIUM; ELYMUS REPENS ROOT; URTICA URENS; WYETHIA HELENIOIDES ROOT; ONION; AMBROSIA ARTEMISIIFOLIA; AMMONIUM CARBONATE; ARALIA RACEMOSA ROOT; ARSENIC TRIOXIDE; ARTEMISIA VULGARIS ROOT; BELLIS PERENNIS; BERBERIS VULGARIS ROOT BARK; BRYONIA ALBA ROOT; CHELIDONIUM MAJUS; EUPATORIUM PERFOLIATUM FLOWERING TOP; EUPHRASIA STRICTA; GELSEMIUM SEMPERVIRENS ROOT; CALCIUM SULFIDE; HISTAMINE DIHYDROCHLORIDE; POTASSIUM DICHROMATE; POTASSIUM IODIDE; LACHESIS MUTA VENOM; LYCOPodium CLAVATUM SPORE; SODIUM CHLORIDE; SCHOENOCaulon OFFICINALE SEED; SOLIDAGO VIRGAUREA FLOWERING TOP; TRILLIUM ERECTUM ROOT; USTILAGO MAYDIS; APIS MELLIFERA; ECHINACEA, UNSPECIFIED; GOLDENSEAL; TARAXACUM OFFICINALE	
<i>Strength Number</i>	30; 15; 15; 15; 15; 15; 15; 15; 15; 3; 3; 3; 3	These are the strength values (to be used with units below) of each active ingredient, listed in the same order as the SubstanceName field above.



<i>Pharmaceutical Classes</i>	Non-Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell-mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Non-Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell-mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Non-Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell-mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell-mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell-mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Standardized Pollen Allergenic Extract [EPC],Non-Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell-mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Non-Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell-mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Non-Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell-mediated Immunity [PE],Increased IgG	These are the reported pharmaceutical class categories corresponding to the SubstanceNames listed above.
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	Production [PE],Pollen [CS],Allergens [CS],Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell- mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell- mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Non- Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell- mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Non- Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell- mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell- mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Non- Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell- mediated Immunity [PE],Increased IgG Production [PE],Pollen [CS],Allergens [CS],Non- Standardized Pollen Allergenic Extract [EPC],Increased Histamine Release [PE],Cell- mediated Immunity [PE],Increased IgG	
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<i>Status</i>	Deprecated	<p>Possible status values:</p> <ul style="list-style-type: none"> <li>&lt;ul&gt;</li> <li>&lt;li&gt;&lt;strong&gt;Active&lt;/strong&gt; &lt;br/&gt;Active NDC Code&lt;/li&gt;</li> <li>&lt;li&gt;&lt;strong&gt;Deprecated&lt;/strong&gt; &lt;br/&gt;Deprecated NDC Code&lt;/li&gt;</li> <li>&lt;li&gt; <ul style="list-style-type: none"> <li>&lt;strong&gt;Unfinished&lt;/strong&gt; (Unapproved)</li> </ul> </li> </ul> <p>&lt;br/&gt;The following status describes submitted unfinished drugs, including the marketing categories of Active Pharmaceutical Ingredient (API), Drug for Further Processing, Bulk for Human Drug Compounding, and Bulk for Animal Drug Compounding.</p> <p>&lt;br/&gt;</p> <p>&lt;strong&gt;</p> <p>FDA does not review and approve unfinished products. Therefore, all products having "unfinished" status are considered unapproved.</p> <p>&lt;/strong&gt;</p> <p>&lt;/li&gt;</p> <p>&lt;/ul&gt;</p>
<i>Last Update Date</i>	2020-01-01	The date that a record was last updated or changed.

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For all questions regarding this bundle please contact [Support@DataLabs.Health](mailto:Support@DataLabs.Health). Also feel free to let us know about any suggestions or concerns. All additional information as well as customer support is available at <https://www.datalabs.health/>.