55714-2315-0
FOOD ALLERGY - ADDITIVE
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.

55714-2315-0 Food Allergy - Additive

Labeler Name	Newton Laboratories, Inc.	Name of Company corresponding to the labeler code segment of the ProductNDC.
NDC Package Code	55714-2315-0	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.
Proprietary Name	Food Allergy - Additive	Also known as the trade name. It is the name of the product chosen by the labeler.
11 Digit NDC Code	55714-2315-00	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.
Product NDC	55714-2315	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.
Product Type Name	HUMAN OTC 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 www.fda.gov/edrls under Structured Product Labeling Resources.
Non Proprietary Name	E102 Tartrazine, E104 Quinoline Yellow, E110 Sunset/orange Yellow, E122 Carmoisine, E123 Armaranth, E124 Cochineal Red A, E127 Erythrosine, D128 Red 2g, E 132 Indigotine, E141 Copper/chlorophyll Complex, E142 Green S, E211 Sodium Benzoate, E212 Potassium Benzoate, E216 Propyl P-hydroxybenzoate, E223 Sodium Metabisulphate, E231 Orthophenylphenol, E250 Sodium Nitrate, E300 Ascorbic Acid, E399 Sodium Mono/bi/triphosphate, E951 Aspartame, Monosodium Glutamate, Beef, Pork, Lamb, Chicken, Turkey, Clam	Sometimes called the generic name, this is usually the active ingredient(s) of the product.
Package Description	7 g in 1 BOTTLE, GLASS (55714-2315-0)	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.

Marketing Category Name	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 www.fda.gov/edrls under Structured Product Labeling Resources.
Product Marketing Start Date	20110301	This is the date that the labeler indicates was the start of its marketing of the drug product.
Dosage Form Name	PELLET	The translation of the DosageForm Code submitted by the firm. The complete list of codes and translations can be found www.fda.gov/edrls under Structured Product Labeling Resources.
Route Name	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 www.fda.gov/edrls under Structured Product Labeling Resources.

Substance Name	EGG; FD&C YELLOW NO. 5; D&C YELLOW NO. 10; FD&C YELLOW NO. 6; CARMOISINE; AMARANTH; PONCEAU 4R; FD&C RED NO. 3; ACID RED 1; FD&C BLUE NO. 2; SODIUM COPPER CHLOROPHYLLIN; ACID GREEN 50; SODIUM BENZOATE; POTASSIUM BENZOATE; PROPYLPARABEN; SODIUM DITHIONATE; 2-PHENYLPHENOL; SODIUM NITRITE; ASCORBIC ACID; SODIUM TRIPOLYPHOSPHATE; ASPARTAME; MONOSODIUM GLUTAMATE; BEEF; PORK; LAMB; CHICKEN; TURKEY; QUAHOG, UNSPECIFIED; CRAB LEG, UNSPECIFIED; OYSTER, UNSPECIFIED; SHRIMP, UNSPECIFIED; SCALLOP, UNSPECIFIED; AMANITA MUSCARIA FRUITING BODY; ONION; GARLIC; ANACARDIUM OCCIDENTALE FRUIT; LYCOPERDON UTRIFORME FRUITING BODY; CAFFEINE; CAPSICUM; CINNAMON; CYNARA SCOLYMUS LEAF; ALPINE STRAWBERRY; ABRUS PRECATORIUS SEED; GLYCYRRHIZA GLABRA; MENTHA PIPERITA; NUTMEG; LACTOSE; BLACK MUSTARD SEED; SOLANUM NIGRUM WHOLE; ALLYLTHIOUREA; USTILAGO MAYDIS; GINGER; BRAZIL NUT; HAZELNUT, UNSPECIFIED; PEANUT; TROUT, UNSPECIFIED; COD, UNSPECIFIED; TUNA, UNSPECIFIED; SALMON, UNSPECIFIED; HERRING, UNSPECIFIED; HISTAMINE DIHYDROCHLORIDE; SOLANUM LYCOPERSICUM; SACCHARIN; SOLANUM	This is the active ingredient list. Each ingredient name is the preferred term of the UNII code submitted.

	TUBEROSUM; SACCHAROMYCES CEREVISIAE; ACONITUM NAPELLUS; ANTIMONY TRISULFIDE; ARSENIC TRIOXIDE; BAPTISIA TINCTORIA ROOT; CINCHONA OFFICINALIS BARK; GELSEMIUM SEMPERVIRENS ROOT; IPECAC; LACHESIS MUTA VENOM; LEDUM PALUSTRE TWIG; LYCOPODIUM CLAVATUM SPORE; SODIUM CHLORIDE; PHOSPHORUS; PODOPHYLLUM; PULSATILLA VULGARIS; TOXICODENDRON PUBESCENS LEAF; SEPIA OFFICINALIS JUICE; SULFUR; URTICA URENS; IRIS VERSICOLOR ROOT; SOLIDAGO VIRGAUREA FLOWERING TOP	
Strength Number	60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 60; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 15; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 10; 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.

Strength Unit	[hp_X]/g; [hp_X]/g	These are the units to be used with the strength values above, listed in the same order as the SubstanceName and SubstanceNumber.

Status	Deprecated	Possible status values: - Active Active NDC Code - Deprecated Deprecated NDC Code Unfinished (Unapproved) 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. FDA does not review and approve unfinished products. Therefore, all products having "unfinished" status are considered unapproved.
Last Update Date	2020-01-01	The date that a record was last updated or changed.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance, Immediate Office
Drug Registration and Listing Team
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
Email: eDRLS@fda.hhs.gov

For all questions regarding this bundle please contact 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/.