58809-209-04
TEXACLEAR HOMEOPATHIC ALLERGY RELIEF
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.

58809-209-04 Texaclear Homeopathic Allergy Relief

Labeler Name	GM Pharmaceuticals, INC	Name of Company corresponding to the labeler code segment of the ProductNDC.
NDC Package Code	58809-209-04	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	Texaclear Homeopathic Allergy Relief	Also known as the trade name. It is the name of the product chosen by the labeler.
11 Digit NDC Code	58809-0209-04	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	58809-209	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.
Proprietary Name Suffix	Cedar Fever	A suffix to the proprietary name, a value here should be appended to the ProprietaryName field to obtain the complete name of the product. This suffix is often used to distinguish characteristics of a product such as extended release (“XR”) or sleep aid (“PM”). Although many companies follow certain naming conventions for suffices, there is no recognized standard.
Non Proprietary Name	Over 100 Extracts	Sometimes called the generic name, this is usually the active ingredient(s) of the product.
Package Description	118 mL in 1 BOTTLE, DROPPER (58809-209-04)	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	20200831	This is the date that the labeler indicates was the start of its marketing of the drug product.
Product Marketing End Date	20250101	This is the date the product will no longer be available on the market. If a product is no longer being manufactured, in most cases, the FDA recommends firms use the expiration date of the last lot produced as the EndMarketingDate, to reflect the potential for drug product to remain available after manufacturing has ceased. Products that are the subject of ongoing manufacturing will not ordinarily have any EndMarketingDate. Products with a value in the EndMarketingDate will be removed from the NDC Directory when the EndMarketingDate is reached.
Dosage Form Name	SOLUTION/ DROPS	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	ACACIA POLLEN; ACER NEGUNDO POLLEN; ACER RUBRUM POLLEN; ACER SACCHARINUM POLLEN; ACER SACCHARUM POLLEN; AGROSTIS GIGANTEA POLLEN; AILANTHUS ALTISSIMA POLLEN; ALLENROLFEA OCCIDENTALIS POLLEN; ALNUS INCANA SUBSP. RUGOSA POLLEN; ALNUS RHOMBIFOLIA POLLEN; AMARANTHUS HYBRIDUS POLLEN; AMARANTHUS PALMERI POLLEN; AMARANTHUS RETROFLEXUS POLLEN; AMARANTHUS SPINOSUS POLLEN; AMARANTHUS TUBERCULATUS POLLEN; AMBROSIA ACANTHICARPA POLLEN; AMBROSIA ARTEMISIIFOLIA POLLEN; AMBROSIA BIDENTATA POLLEN; AMBROSIA CONFERTIFLORA POLLEN; AMBROSIA DUMOSA POLLEN; AMBROSIA PSILOSTACHYA POLLEN; AMBROSIA TRIFIDA POLLEN; ANTHOXANTHUM ODORATUM POLLEN; ARTEMISIA ANNUA POLLEN; ARTEMISIA LUDOVICIANA WHOLE; ARTEMISIA TRIDENTATA POLLEN; ARTEMISIA VULGARIS WHOLE; ATRIPLEX CANESCENS POLLEN; AVENA SATIVA POLLEN; BACCHARIS HALIMIFOLIA WHOLE; BAPTISIA TINCTORIA ROOT; BASSIA SCOPARIA POLLEN; BETULA LENTA POLLEN; BETULA NIGRA POLLEN; BETULA OCCIDENTALIS WHOLE; BROMUS INERMIS POLLEN; BROUSSONETIA PAPYRIFERA POLLEN; CARPINUS CAROLINIANA WHOLE; CARYA ALBA POLLEN; CARYA CORDIFORMIS WHOLE; CARYA GLABRA	This is the active ingredient list. Each ingredient name is the preferred term of the UNII code submitted.

	POLLEN; CARYA ILLINOINENSIS POLLEN; CARYA LACINIOSA POLLEN; CARYA OVATA POLLEN; CEDRUS DEODARA WOOD; CELTIS OCCIDENTALIS POLLEN; CHENOPODIUM ALBUM POLLEN; CUPRESSUS ARIZONICA POLLEN; CYCLACHAENA XANTHIFOLIA POLLEN; CYNODON DACTYLON POLLEN; DACTYLIS GLOMERATA POLLEN; DISTICHLIS SPICATA POLLEN; ECHINACEA, UNSPECIFIED; ELYMUS REPENS POLLEN; FAGUS GRANDIFOLIA POLLEN; FESTUCA PRATENSIS POLLEN; FRAXINUS AMERICANA POLLEN; FRAXINUS PENNSYLVANICA POLLEN; FRAXINUS VELUTINA POLLEN; GUTIERREZIA SAROTHRAE WHOLE; HOLCUS LANATUS POLLEN; HYDRASTIS CANADENSIS WHOLE; IVA ANGUSTIFOLIA POLLEN; IVA ANNUA POLLEN; JUGLANS NIGRA POLLEN; JUNIPER BERRY; JUNIPERUS ASHEI POLLEN; JUNIPERUS DEPPEANA WHOLE; JUNIPERUS MONOSPERMA POLLEN; JUNIPERUS OSTEOSPERMA POLLEN; JUNIPERUS PINCHOTII POLLEN; JUNIPERUS SCOPULORUM POLLEN; JUNIPERUS VIRGINIANA POLLEN; LIGUSTRUM LUCIDUM WHOLE; LIQUIDAMBAR STYRACIFLUA POLLEN; LOLIUM MULTIFLORUM POLLEN; LOLIUM PERENNE POLLEN; MELALEUCA QUINQUENERVIA POLLEN; MORUS ALBA WHOLE; MORUS RUBRA POLLEN; MYRRH; OSTRYA VIRGINIANA WHOLE; PASCOPYRUM	

	SMITHII POLLEN; PASPALUM NOTATUM POLLEN; PHALARIS ARUNDINACEA POLLEN; PHLEUM PRATENSE POLLEN; PHYTOLACCA AMERICANA ROOT; PINUS NIGRA POLLEN; PINUS PONDEROSA POLLEN; PINUS STROBUS BARK; PINUS STROBUS POLLEN; PINUS SYLVESTRIS POLLEN; PINUS TAEDA POLLEN; PLANTAGO LANCEOLATA POLLEN; PLATANUS OCCIDENTALIS POLLEN; POA ANNUA POLLEN; POA PRATENSIS POLLEN; POPULUS ALBA POLLEN; POPULUS DELTOIDES SUBSP. DELTOIDES POLLEN; POPULUS DELTOIDES SUBSP. MONILIFERA POLLEN; POPULUS FREMONTII POLLEN; POPULUS NIGRA POLLEN; PROSOPIS PALLIDA POLLEN; QUERCUS ALBA WHOLE; QUERCUS GAMBELII POLLEN; QUERCUS MACROCARPA POLLEN; QUERCUS NIGRA POLLEN; QUERCUS RUBRA BARK; QUERCUS STELLATA POLLEN; QUERCUS VELUTINA WHOLE; QUERCUS VIRGINIANA POLLEN; RORIPPA NASTURTIUM-AQUATICUM; RUMEX ACETOSELLA POLLEN; RUMEX CRISPUS POLLEN; SALIX NIGRA POLLEN; SALSOLA KALI WHOLE; SECALE CEREALE POLLEN; SOLIDAGO CANADENSIS WHOLE; SORGHUM HALEPENSE POLLEN; SORGHUM X DRUMMONDII WHOLE; TAMARIX GALLICA POLLEN; TAXODIUM DISTICHUM POLLEN; THUJA OCCIDENTALIS LEAF; THUJA PLICATA LEAF; TRIADICA SEBIFERA WHOLE; TRIGONELLA FOENUM-	

	GRAECUM WHOLE; TRITICUM AESTIVUM POLLEN; ULMUS AMERICANA POLLEN; ULMUS CRASSIFOLIA POLLEN; ULMUS CRASSIFOLIA WHOLE; ULMUS PUMILA POLLEN; URTICA DIOICA POLLEN; XANTHIUM STRUMARIUM POLLEN; ZEA MAYS POLLEN	
Strength Number	12; 12; 12; 12; 12; 6; 12; 30; 12; 12; 30; 30; 30; 30; 30; 30; 30; 30; 30; 30; 30; 30; 6; 30; 30; 6; 30; 30; 6; 12; 5; 30; 12; 12; 12; 6; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 30; 12; 30; 6; 6; 6; 5; 6; 12; 6; 12; 12; 12; 30; 6; 5; 30; 30; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 6; 6; 12; 12; 12; 5; 12; 12; 6; 6; 6; 5; 12; 12; 12; 12; 12; 12; 30; 12; 6; 6; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 12; 30; 12; 5; 30; 30; 12; 30; 6; 30; 6; 12; 12; 12; 12; 12; 12; 5; 6; 12; 12; 12; 12; 30; 30; 6	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]/mL; [hp_X]/mL;	These are the units to be used with the strength values above, listed in the same order as the SubstanceName and SubstanceNumber.

	[hp_X]/mL; [hp_X]/mL; [hp_X]/mL; [hp_X]/mL; [hp_X]/mL; [hp_X]/mL	

Pharmaceutical Classes	Allergens [CS], Allergens [CS],	These are the reported pharmaceutical class categories corresponding to the SubstanceNames listed above.

	Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Allergens [CS], Cell-mediated Immunity [PE],	

	Cell-mediated Immunity [PE], Cell-mediated Immunity [PE]	

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	2025-01-02	The date that a record was last updated or changed.

Food and Drug Administration
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