

17314-575-00

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.

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<i>Labeler Name</i>	Janssen Ortho LLC	Name of Company corresponding to the labeler code segment of the ProductNDC.
<i>NDC Package Code</i>	17314-575-00	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>11 Digit NDC Code</i>	17314-0575-00	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

<i>Strength Number</i>	100	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>Strength Unit</i>	mg/1	These are the units to be used with the strength values above, listed in the same order as the SubstanceName and SubstanceNumber.
<i>Status</i>	Unfinished	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. <br/&gt

Food and Drug Administration
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Office of Compliance, Immediate Office
Drug Registration and Listing Team
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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/>.