

**NDA 18-662**  
**ACCUTANE® (isotretinoin) Capsules**  
**Annual Report**

49

Distribution Data

The following table indicates the quantity of drug product distributed under the approved application.

National Drug Code/ National Stock Number/ Dosage Form/ Packaging Unit	U.S. Total # of Package Units	Non-U.S. Total # of Package Units
NDC 0004-0155-49 NSN 6505-01-292-9831 10 mg capsules Rx Pak of 10 x 10	38,382 Rx Pak of 10 x 10	Not Exported
NDC 0004-0169-49 NSN 6505-01-328-9658 20 mg capsules Rx Pak of 10 x 10	168,096 Rx Pak of 10 x 10	Not Exported
NDC 0004-0156-49 NSN 6505-01-292-9832 40 mg capsules Rx Pak of 10 x 10	448,372 Rx Pak of 10 x 10	Not Exported

CONFIDENTIAL

**NDA 18-662**  
**ACCUTANE® (isotretinoin) Capsules**  
**Annual Report**

**Current Package Labeling**

Included is the package insert and labeling representative of that used during the reporting period.

COMPONENT	IDENTIFICATION NUMBER	COMMENTS
Package insert	27897997-1001 27898140-0202 - (Not implemented during report period)	Changed from 27897043-0500 Changed from 27897997-1001
Blister Backing: 10 mg 20 mg 40 mg	15-34-24993285-0698 15-34-24993288-0698 15-34-24993291-0698	No change No change No change
Blister Packages: 10 mg capsule 20 mg capsule 40 mg capsule	27897040-0500 27897041-0500 27897042-0500	No change No change No change
Cartons: 10 mg capsule 20 mg capsule 40 mg capsule	27898090-1101 27898091-1101 27898092-1101	Changed from: 27897057-0200 27897058-0200 27897059-0200
Drum Labels: (for Shipment of Concentrate from HLR, Nutley, NJ to R.P.Scherer, St. Petersburg, FL)  10 mg concentrate 20 mg concentrate 40 mg concentrate	25083933-0898 26275348-0898 25934612-0898	No change

Labeling components that are part of the S.M.A.R.T. Program have been submitted in Supplement S-044. They are not included, but will be provided upon request.

HLR 033014