

1. SPL Marketing Category Terminology: SPL manufacturer files using one of the “manufactured exclusively” categories (not made publicly available [manufacture- only SPL]).

SPL Marketing Category Terminology Update			
Replacement		To Be Replaced	
Marketing Category Term	NCI Concept Code	Marketing Category Term	NCI Concept Code
Approved Drug Product Manufactured Under Contract	C132333	Approved Drug Product Manufactured Exclusively for Private Label Distributor	C95600
OTC Monograph Drug Product Manufactured Under Contract	C132334	OTC Monograph Drug Product Manufactured Exclusively for Private Label Distributor	C95601
Unapproved Drug Product Manufactured Under Contract	C132335	Unapproved Drug Product Manufactured Exclusively for Private Label Distributor	C95602

Terminology posted to the SPL Resources webpage:

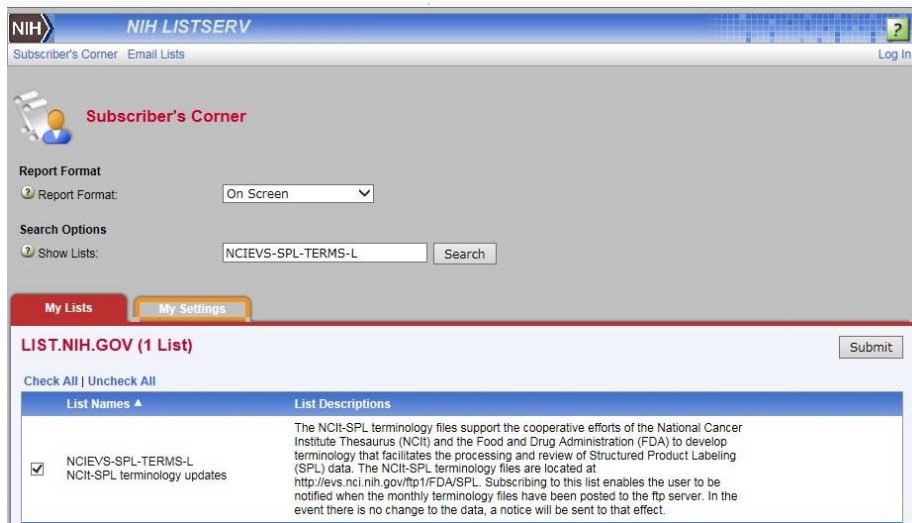
<https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162528.htm>

2. New Business Operation Qualifiers are now available <https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm321788.htm>. Manufactures Human Over-The-Counter Drug Products to be deprecated, and replaced with these three:

Manufactures human over-the-counter drug products not produced under an approved drug application or under a monograph	C131710
Manufactures human over-the-counter drug products produced under a monograph	C131708
Manufactures human over-the-counter drug products produced under an approved drug application	C131709

- There will be a time where the terms will overlap (several months at minimum)

3. Route of Administration: Intracanalicular [C1327373] - <https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.htm>
4. GDUFA term (additional Business Operation Qualifier): Contract Manufacture for GDUFA Files. Will be posted to SPL Resources page soon
 - For notifications to updates to NCI terms: go to list.nih.gov - <https://list.nih.gov/>
 - Sign in. If you’ve not signed up for any of the NIH listservs before, you may need to set up access.
 - Search for NCIEVS-SPL-TERMS-L



- Click the check box. Click Submit button

5. Country code terms are being transitioned from ISO-3166 Country Code list to GENC Codes (aka Country Codes). Full list at the State Department Site:

<https://www.state.gov/s/inr/rls/10543.htm>

See Note 1 <https://www.state.gov/s/inr/rls/10543.htm#note1> : Geopolitical Entities, Names, and Codes (GENC) Standard two-letter and three-letter codes. GENC is the replacement standard for FIPS 10-4 and is the U.S. Government profile of the ISO 3166 international country code standard. For more information on GENC please see

<https://nsgreg.nga.mil/genc/discovery>.