

The following are examples of Typical Data sets Filers are required to submit to FDA in ACE

for a Biological Product	<b>Data submitted by Filer:</b>
Intended Use Code:	<b>080.000</b>
CBP required: Product Description	<b>Rubella vaccine</b>
Product code:	<b>57CH-99</b>
Country of Production	<b>DE</b>
CBP required Manufacturer (name/address)	<b>Baxter AG, Industriestasse 72, Munich, Germany</b>
CBP required Shipper (name/address):	<b>Baxter AG, Industriestasse 72, Munich Germany</b>
CBP required Consignee (name/address):	<b>Baxter Healthcare Corp. Deerfield, IL 60015</b>
Importer (name/Contact):	<b>Earl, Adolph David 1-800-423-2090 ADEARL@Baxter.com</b>
Specific product data:	<b>BLN 1026 STN 10656</b>

for a Drug Product	<b>Data submitted by Filer:</b>
Intended Use Code:	<b>180.009</b>
CBP required: Product Description	<b>Acetaminophen</b>
Product code:	<b>60LIC01</b>
Country of Production	<b>DE</b>
CBP required Manufacturer (name/address)	<b>Baxter AG, Industriestasse 72, Munich, Germany</b>
CBP required Shipper (name/address):	<b>Baxter AG, Industriestasse 72, Munich Germany</b>
CBP required Consignee (name/address):	<b>Baxter Healthcare Corp. Deerfield, IL 60015</b>
Importer (name/Contact):	<b>Earl, Adolph David 1-800-423-2090 ADEARL@Baxter.com</b>
Specific product data:	<b>IND 058907</b>

for a Medical Device Product	<b>Data submitted by Filer:</b>
Intended Use Code:	<b>081.001</b>
CBP required: Product Description	<b>Myocardial Pacing Lead</b>
Product code:	<b>74N--HW</b>
Country of Production	<b>DE</b>

CBP required Manufacturer (name/address)	<b>Richard Wolf GMBH, Wurttemberg, Germany</b>
CBP required Shipper (name/address):	<b>Greybatch Medical, 2300 Berkshire Lane Minneapolis, MN 55441</b>
CBP required Consignee (name/address):	<b>Greybatch Medical, 2300 Berkshire Lane Minneapolis, MN 55441</b>
Importer (name/Contact):	<b>Earl, Adolph David 1-800-423-2090 ADEARL@Greybatch.com</b>
Specific product data:	<b>DEV 1234567 DFE 2345678 LST E12345</b>

for a Cosmetic Product	<b>Data submitted by Filer:</b>
Intended Use Code:	<b>UNK</b>
CBP required: Product Description	<b>Eye Shadow</b>
Product code:	<b>53CD-03</b>
Country of Production	<b>CA</b>
CBP required Manufacturer (name/address)	<b>Bare Escentualse, 2960 Kingsway Dr. Ont, CA N2C 1X1</b>
CBP required Shipper (name/address):	<b>Bare Escentualse, 2960 Kingsway Dr. Ont, CA N2C 1X1</b>
CBP required Consignee (name/address):	<b>Bare Escentualse, 71 Stevens Dr, SanFrancisco, CA 94105</b>
Importer (name/Contact):	<b>Earl, Adolph David 1-800-423-2090 ADEARL@BareMineral.com</b>
Specific product data:	<i>n/a</i>

for a Tobacco Product	<b>Data submitted by Filer:</b>
Intended Use Code:	<b>UNK</b>
CBP required: Product Description	<b>Cigar tobacco leaves</b>
Product code:	<b>98BAA01</b>
Country of Production	<b>MX</b>
CBP required Manufacturer (name/address)	<b>Excaliber Tobacco, Mexico City, MX 11122</b>
CBP required Shipper (name/address):	<b>General Tobacco Co, 230 Berkshire Ln, San Francisco CA 94105</b>
CBP required Consignee (name/address):	<b>General Tobacco Co, 230 Berkshire Ln, San Francisco CA 94105</b>

Importer (name/Contact):	<b>Earl, Adolph David 1-800-423-2090</b> <b>ADEARL@GenTobacco.com</b>
Specific product data:	<i>n/a</i>