



FDA Product Data Sheet: Biologics

Account Number		Account Name	
DUNS Number <i>(if available)</i>		Client Part Number*	
Description of Product <i>(as complete as possible)</i>			
Government Agency Processing Code		Tariff Number	
FDA Product Code <i>(if known)</i>		Country of Origin**	FDA Country of Production**
Cargo Storage Status	Intended Use		
Name of active ingredient(s) in prescription, over the counter, animal, drugs or medicated animal feeds:			

* Part number as shown on Customs document to identify the product (item number, SKU, etc.)

** U.S. Customs considers the country of origin to be the country where the product last underwent a "substantial transformation" (resulting in an increase in value.) The FDA considers the country of origin to be that of the actual manufacturer. Actual manufacturer is defined as the last party involved in the production process.

FDA Actual Manufacturer

Company Name			
Address			City
State/Province	Zip/Postal Code	Country	DUNS Number <i>(if available)</i>

Manufacturer/Exporter Registration Numbers *Provide registration numbers for all applicable*

DA: New Drug, Abbreviated New Drug	PM#: Biologics Premarket Notification Number 501K
IND: Biologic Investigation New Drug Application Number	HRN: Biologic Cells, Tissues Product Establishment Registration
STN: Biological Submission Tracking Number	BLN: Biologic License Number
Other:	

FDA Shipper *(As shown on Customs document, BOL or airway bill)*

Company Name			
Address			City
State/Province	Zip/Postal Code	Country	DUNS Number <i>(if available)</i>