


<b>4. Proprietary Name</b> The name of the product. Can be very-very long.	<b>5. Established Name</b> The name of the product. <b>Product Code No.:</b> A13123919231
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<b>6. Package Insert Date and ID Number</b> (Latest final printed labeling) 2019-04-01 12312	<b>7. Manufacturer Name</b> Some Company Name Inc <b>License No. (Biologics):</b> GB21231
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a. Please check only one:	Professional	Consumer
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Material Type (use FDA codes) b.	Dissemination/ Publication Date c.	Material ID Code d.	Material Description e.
Audio	21.04.2001	F1231	Some long text here. Some long text here. Some long text here. Some long text here. Some long text here.
Book	21.04.2001	F1231	Some long text here. Some long text here. Some long text here. Some long text here. Some long text here.
CD-ROM	21.04.2001	F1231	Some long text here. Some long text here. Some long text here. Some long text here. Some long text here.
File Card	21.04.2001	F1231	Some long text here. Some long text here. Some long text here. Some long text here. Some long text here.

[illegible]

<b>9. Applicant's (or Agent's) Return Address</b>		<b>10. Responsible Official's (or Agent's)</b>	
<b>Address 1 (Street address, P.O. box, company name c/o)</b> 61 North Summit Street <b>Address 2 (Apartment, suite, unit, building, floor, etc.)</b> Suite 312/F <b>City</b> Kansas City <b>Country</b> United States		<b>State/Province/Region</b> Missouri <b>ZIP or Postal Code</b> 64030	
		<b>a. Telephone Number (Include area code)</b> +37291923121 <b>b. FAX Number (Include area code)</b> +37213123191923 <b>c. Email Address</b> john.smith@companyname.com	
<b>11. Typed Name and Title of Responsible Official or Agent</b> John von Longname Smith		<b>12. Signature of Responsible Official or Agent</b> 	
		<b>13. Date</b> 23.04.2019	
<b>14. For CBER Products Only (Check one)</b> <div style="text-align: center;"> <input type="checkbox"/> Draft      <input type="checkbox"/> Final         </div>			
<p style="text-align: center;">This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p style="text-align: center;">*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 2 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">         Department of Health and Human Services          Food and Drug Administration          Office of Chief Information Officer          Paperwork Reduction Act (PRA) Staff          PRAStaff@fda.hhs.gov       </p> <p style="text-align: center;">"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."</p>			