

4. Proprietary Name The name of the product. Can be very-very long.	5. Established Name The name of the product. Product Code No.: A13123919231
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6. Package Insert Date and ID Number (Latest final printed labeling) 2019-04-01 12312	7. Manufacturer Name Some Company Name Inc License No. (Biologics): GB21231
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8.	Advertisement / Promotional Labeling Materials
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a. Please check only one: Professional Consumer

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.

f. Comments

[illegible]

9. Applicant's (or Agent's) Return Address		10. Responsible Official's (or Agent's)	
Address 1 (Street address, P.O. box, company name c/o) 61 North Summit Street Address 2 (Apartment, suite, unit, building, floor, etc.) Suite 312/F City Kansas City Country United States		State/Province/Region Missouri ZIP or Postal Code 64030	
		a. Telephone Number (Include area code) +37291923121 b. FAX Number (Include area code) +37213123191923 c. Email Address john.smith@companyname.com	
11. Typed Name and Title of Responsible Official or Agent John von Longname Smith		12. Signature of Responsible Official or Agent 	
		13. Date 23.04.2019	
14. For CBER Products Only (Check one) <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>			