

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration  <b>TRANSMITTAL OF ADVERTISEMENTS                  AND PROMOTIONAL LABELING FOR                  DRUGS AND BIOLOGICS                  FOR HUMAN USE</b>	<b>1. Date Submitted</b> 22.04.2019	<b>3. NDA/ANDA/AADA or BLA/PMA</b> Type: Some type      Number: XYZ1231 Single product      Multiple products For multiple products, submit completed form and specimen of advertising/promotional materials to one application of choice, and attach separate sheet addressing items 3-5 for remainder of products. Refer to No. 3 on instruction sheet.
	<b>2. Label Review Number (Biologics)</b> 12312A1BCD	

**NOTE: Form FDA 2253 is required by law. Reports are required for approved NDAs and ANDAs (21 CFR 314.81).**

<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 (Latest final printed labeling)</b> 2019-04-01 12312	<b>7. Manufacturer Name</b> Some Company Name Inc <b>License No. (Biologics):</b> GB21231
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**8. Advertisement / Promotional Labeling Materials**

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.
Book	21.04.2001	F1231	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.
File Card	21.04.2001	F1231	Some long text here. Some long text here. Some long text here. Some long text here.

**f. Comments**

This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit. This can be a very-ver long test. Just fill it with some random words, repeat and profit.

<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> <span style="float: right;"><b>State/Province/Region</b></span> Kansas City <span style="float: right;">Missouri</span> <b>Country</b> <span style="float: right;"><b>ZIP or Postal Code</b></span> United States <span style="float: right;">64030</span>		<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>		<b>12. Signature of Responsible Official or Agent</b>	<b>13. Date</b>
John von Longname Smith			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>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></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            PRASStaff@fda.hhs.gov         </p> <p>"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>			