Form Approved: OMB No. 0910-0001, Expiration Date: March 31, 2021; see PRA Statement on last page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE

1. Date Submitted
22.04.2019

2. Label Review Number (Biologics)
12312A1BCD

3. NDA/ANDA/AADA or BLA/PMA
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.

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

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

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

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. 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. 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. 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. 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.

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		**a. Telephone Number (Include area code)** +37291923121
Address 2 (Apartment, suite, unit, building, floor, etc.) Suite 312/F		**b. FAX Number (Include area code)** +37213123191923
City Kansas City	**State/Province/Region** Missouri	**c. Email Address** john.smith@companyname.com
Country United States	**ZIP or Postal Code** 64030	

11. Typed Name and Title of Responsible Official or Agent	12. Signature of Responsible Official or Agent	13. Date
John von Longname Smith		23.04.2019

14. For CBER Products Only (Check one)

❑ Draft ■ Final

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."