DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Form Approved: OMB No. 0910-0001
Expiration Date: March 31, 2024
See PRA Statement on last page.

1. Date Submitted

2. Application Information — 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.

Application Type:

Application Number:

NDA
ANDA
BLA
PMA
CDER IND

NOTE: Form FDA 22 ports are required for approved NDAs, ANDAs (21 CFR 314.81), and BLAs (601.12(f)(4))

3. Proprietary Name	4. Established Name Product Code No.:
5. Package Insert Date and ID Number (Latest final printed labeling)	6. Manufacturer Name License No. (Biologics):

7. **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.	
				Delete Row

To delete a row, click the "Delete Row" button for that row (or press the enter key if you've tabbed into the button). You cannot delete the last remaining row. **Add New Row**

f. Comments

8. Applicant's (or Agent's) Return Address

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

9. Responsible Official's (or Agent's)

a. Telephone Number *(Include area code)*

b. FAX Number *(Include area code)*

c. Email Address

PSC Publishing Services (301) 443-6740 EF

10. Typed Name and Title of Responsible Official or Agent	11. Signature of Responsible Official or Agent	12. Date
	Sign	
13. 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."