

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration				Form Approved: OMB No. 0910-0001 Expiration Date: March 31, 2024 See PRA Statement on last page.	
TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE				1. Date Submitted	
2. Application Information		Single product		Multiple products	
Application Type:				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 Number:					
NOTE: Form FDA 2253 (04/21) Reports 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				9. Responsible Official's (or Agent's)	
Address 1 (Street address, P.O. box, company name c/o)				a. Telephone Number (Include area code)	
Address 2 (Apartment, suite, unit, building, floor, etc.)				b. FAX Number (Include area code)	
City		State/Province/Region			
Country		ZIP or Postal Code			

10. Typed Name and Title of Responsible Official or Agent	11. Signature of Responsible Official or Agent Sign	12. Date
13. For CBER Products Only (<i>Check one</i>) 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
PRASStaff@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."