Form Approved: OMB No. 0910-0001, Expiration Date: May 31, 2011; see OMB Statement on Page 3.

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

1. DATE SUBMITTED

2. LABEL REVIEW NO. (Biologics)

3. NDA/ANDA/AADA OR BLA/PLA/PMA
Number:
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 2253 is required by law. Reports are required for approved NDAs and ANDAs (21 CFR 314.81)

4. PROPRIETARY NAME	5. ESTABLISHED NAME Prod. Code No.
6. PACKAGE INSERT DATE and ID NO. (Latest final printed labeling)	7. MANUFACTURER NAME: License No. (Biologics)

FDA/CBER USE ONLY

REVIEWED BY	DATE	RETURNED BY	DATE

8. **ADVERTISEMENT / PROMOTIONAL LABELING MATERIALS**

Please check only one: ☐ Professional ☐ Consumer

Material Type (use FDA codes) a.	Dissemination/ Publication Date b.	Applicant's Material ID Code and/or description c.	Previous review No. if applicable / date (PLA Submissions) d.	COMMENTS:

9. TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT	10. SIGNATURE OF RESPONSIBLE OFFICIAL
11. APPLICANT'S RETURN ADDRESS	12. RESPONSIBLE OFFICIAL'S a. PHONE NO. b. FAX NO.
	13. FOR CBER PRODUCTS ONLY: *(Check one)* ☐ Part I/Draft ☐ Part II/Final

Instructions for Completing Form FDA 2253

1. Date Submitted - the date the 2253 Form and accompanying materials are sent to the FDA.

2. Original 2567 submission for biologics, leave blank. Resubmissions, include previously assigned "P" review number, if known.

3. NDA/ANDA/AADA/PLA/BLA/PMA number. For CBER, include most recent reference number effecting a labeling change.

   Single product-Each 2253 Form and accompanying submission should pertain to only one application number. The completed Form and the attached submission materials should be prepared in duplicate, and should be separated for ease of handling.

   Multiple products. In cases where promotional materials mention multiple products such as price lists, formulary lists, multiple product reminder ads, and corporate communications; three specimens of the promotional piece may be filed to a single application with three 2253 Forms and labeling, and the other referenced products require only an attached sheet(s) which identifies the other referenced products including: application No., trade name and established name, and labeling for each referenced product.

4. Proprietary Name - enter the proprietary name of the drug or biological product. The dosage form should also be included if it is part of the proprietary name or if it distinguishes the product from other dosage forms with the same trade name.

5. Established Name - the established (generic) name of the drug/biological product. For biological product submissions, provide "Product Code No.", if known or used.

6. Package Insert Date & No. - the date and identification number of the most current approved product labeling (include two copies).

7. Manufacturer name and license no.- provide this information for biological product submissions.

8. Advertising/Promotional Labeling Materials- A detailed listing of all promotional materials submitted on the 2253 Form. Each material should be individually listed per line. Consumer and professional pieces should be submitted separately.

8a. Material Type - List materials submitted using the FDA Codes listed below.

FDA CODE	TRANSLATION
CAD	CONSUMER PRINT ADVERTISEMENTS
CAT	CONSUMER AUDIO (TAPE/SCRIPT)
CCP	CONSUMER COMPUTER DISCS/PROGRAMS/CD ROM
CDM	CONSUMER DIRECT MAIL
CED	CONSUMER PROMOTIONAL LABELING
COT	CONSUMER - OTHER
CRD	CONSUMER RADIO (SCRIPT/TAPE)
CSK	CONSUMER STARTER KITS
CTL	CONSUMER TELEPHONE (SCRIPTS)
CTV	CONSUMER TELEVISION (SCRIPT/STORYBOARD/VIDEO TAPE)
CVT	CONSUMER VIDEO (TAPE/STORYBOARD/SCRIPT)
PAD	PROFESSIONAL PRINT AD
PAT	PROFESSIONAL AUDIO TAPE/CD
PBK	PROFESSIONAL BOOK
PCP	PROFESSIONAL COMPUTER DISCS/PROGRAMS/CD ROMS
PCT	PROFESSIONAL PRICE CATALOGS
PDS	PROFESSIONAL DRUG SAMPLE
PEP	PROFESSIONAL EXHIBIT PANEL
PFC	PROFESSIONAL FILE CARD
PFE	PROFESSIONAL FORMULARY ECONOMIC
PFK	PROFESSIONAL PRINT FORMULARY KIT
PGV	PROFESSIONAL GIVEAWAYS
PHO	PROFESSIONAL HOUSE ORGAN
PLT	PROFESSIONAL DIRECT MAIL (PRESCRIBER/PHARMACIST/WHOLESALER)
PMN	PRODUCT MONOGRAPHS
POT	PROFESSIONAL - OTHER
PPO	PROFESSIONAL PRINT -- OTHER
PPR	PRINT PRESS RELEASE
PRC	PROFESSIONAL REPRINT CARRIERS
PRD	PROFESSIONAL RADIO (SCRIPT/TAPE)
PRP	PROFESSIONAL REPRINTS
PSA	PROFESSIONAL SALES AID (DETAILER)
PSC	PROFESSIONAL SAMPLE CARTON
PSL	PROFESSIONAL SLIDES
PTL	PROFESSIONAL TELEPHONE (SCRIPT)
PTV	PROFESSIONAL TELEVISION (SCRIPT/STORYBOARD/VIDEOTAPE)
PVT	PROFESSIONAL VIDEO TAPE
VNR	VIDEO NEWS RELEASES
WWW	INTERNET PROMOTION
OM	OTHER MISCELLANEOUS (EXPLAIN)

8b. Dissemination/Publication Date- the date of the initial dissemination of the promotional labeling or the date of initial publication for a journal advertisement.

8c. Applicant's Material ID Code- the applicant's identification code or other designation of the specific promotional material.

8d. Previous review No. and date if biological product submission, if applicable.

9. Typed Name and Title of Responsible Official- the individual responsible for responding to any inquires regarding the 2253 submission.

10. Signature of Responsible Official

11. Applicant's Return Address

12a & b. Telephone and FAX Numbers - the telephone and facsimile numbers of the responsible official.

13. Biological products: check #1 if submitting draft; check #2 for final copy.

NOTE: Forward Form and attachments for drugs to: Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communication, 5901-B Ammendale Road, Beltsville, MD 20705
Forward Form and attachments for biologics to: Department of Health and Human Services, Food and Drug Administration, CBER (HFM-202), 1401 Rockville Pike, Rockville, MD 20852-1448.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

Please **DO NOT RETURN** this form to this address.

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 control number.