

<b>TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE</b>	1. DATE SUBMITTED	3. NDA/ANDA/AADA OR BLA/PLA/PMA Number:  Single product <input type="checkbox"/> Multiple products <input type="checkbox"/>  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.
	2. LABEL REVIEW NO. <i>(Biologics)</i>	

**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. <i>(Latest final printed labeling)</i>	7. MANUFACTURER NAME:  License No. <i>(Biologics)</i>

**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: <i>(Check one)</i>  <input type="checkbox"/> Part I/Draft <input type="checkbox"/> 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.

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

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705

*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.*

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