INSTRUCTIONS FOR COMPLETING FORM FDA 2253 – TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE

(The item numbers below correspond to the numbered boxes on Form FDA 2253)

1. **Date Submitted –** The date the 2253 Form and accompanying materials are sent to the FDA. Use drop-down calendar or MM/DD/YYYY format.

2. **Application Information –** Provide the application type (New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Biologics License Application (BLA), or Premarket Approval Application (PMA)) from the drop-down followed by the application number. For CBER BLAs enter the supplement number, if known.

Select either single product or multiple products:

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

- Multiple products – A multiple product submission is used for cases where promotional materials mention multiple products such as price lists, formulary lists, multiple product reminder ads, and corporate communications. A single application number should be listed on the 2253 Form and the other application numbers should be included on an attached sheet(s) which identifies the other referenced products including: application type and number, trade name and established name. Labeling for each referenced product should be included. For non-eCTD and paper submissions, three specimens of the promotional piece should be filed to a single application with three 2253 Forms and labeling, and three copies of the attached sheet(s) showing other referenced products as described above.

3. **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.

4 **Established Name –** The established (generic) name of the drug/biological product. For biological product submissions, provide “Product Code No.”, if known or used.

5. **Package Insert Date and ID Number –** The date and identification number of the most current product labeling (include two copies for paper submissions).

6. **Manufacturer Name and License No. –** Provide the manufacturer name. Also include the license number for biological product submissions.

7. **Advertising/Promotional Labeling Materials –** A detailed listing of all promotional materials submitted on the 2253 Form. Each material should be individually listed per line. Individual components of Formulary Kits and Professional and/or Consumer Kits should be listed separately. Add a new row for each advertisement/ promotional labeling material. Consumer and professional pieces should be submitted separately.

7a. **Professional or Consumer –** Select only one. If the materials are for mixed audiences, select one audience (professional or consumer) based on the intended primary audience. If the materials will be viewed by both professionals and consumers, note this in the Comments section (8f).

7b. **Material Type –** List materials submitted using the FDA Codes listed below (please see next page).

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FDA CODE	TRANSLATION
Audio	Audio Media (e.g. audio formats other than Internet Audio)
Book	Book
Carrier	Reprint Carrier (e.g. a folder or detail piece that houses a reprint)
Carton	Sample Carton (e.g. a box or container that houses a drug sample)
Catalog	Catalog (e.g. a pamphlet or book containing a systematically arranged list or record of items or products)
CD-ROM	CD ROMS/Programs/Discs (e.g. a CD ROM that is distributed to health care professionals or consumers that does not fall into one of the other material types)
Corrective Internet	Corrective Internet (e.g. corrective materials such as websites, Internet audio, or Internet video related to a Warning letter)
Corrective Letter	Corrective Letter (e.g. corrective letter to health care professionals or consumers or other printed correctives related to a Warning letter)
Corrective Print Ad.	Corrective print advertisement related to a Warning letter
Corrective TV.	Corrective TV (e.g. corrective television advertisement related to a Warning letter)
Direct Mail	Direct Mail (e.g. printed non-electronic materials mailed directly to individuals)
Drug Sample	Drug Sample (e.g. a small quantity of prescription drug not intended to be sold and given to prescribers for dissemination to patients)
Electronic Detail Aid.	Electronic Detail Aid (e.g. electronic detail aids, sales aids, or applications used by sales representatives to detail the product)
Exhibit	Exhibit (e.g. electronic or non-electronic item(s) set out for public display such as vertical panels)
File Card	File Card
Form	Form (e.g. form for subsidy or patient support form)
Formulary Economic.	Formulary Economic (e.g. material containing cost information about a product provided to a formulary committee)
Formulary Kit.	Formulary Kit (e.g. packaged set of materials about a product provided to a formulary committee)
Giveaway.	Giveaway
House Organ.	House Organ (e.g. a periodical issued by a company dedicated to presenting news about the firm, its products, or its personnel)
Kit	Kit (e.g. a packaged set of related materials such as a sales kit)
Monograph	Product Monograph
PDURS	Prescription Drug Use Related Software
Press Release.	Press Release
Print Ad	Print Advertisement
Promotional Labeling.	Promotional Labeling (e.g. generally any labeling other than FDA-required labeling that is devised for promotion of the product such as brochures, booklets, or price lists. Use this category when materials do not fall into one of the other material types.)
Radio.	Radio (e.g. audio broadcast over radio waves, can include the script)

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FDA CODE	TRANSLATION
Reply Card	Reply Card
Reprint	Reprint (e.g. a reproduction of printed material that has previously appeared in print)
Sales Aid	Sales Aid (e.g. print sales aid or detail aid)
Slides	Slides (e.g. professional or consumer slide presentations including official notes or mandatory talking points)
Telephone	Telephone (e.g. script for telephone calls)
Training Materials	Training Materials (e.g. learning modules, training video/brochure/other piece(s) provided to health care professionals or patients)
TV	Television Advertisement
Video	Video (e.g. video other than a Video News Release or Internet Video)
Video News Release	Video News Release (e.g. video provided to television newsrooms)
www-audio	Internet Audio (e.g. podcast or audio conference)
www-banner	Internet Banner (e.g. a banner that is intended to be embedded into a web page.)
www-ecomm	Internet Electronic Communication (e.g. email directed to health care professionals or consumers)
www-links	Internet Link (e.g. sponsored links)
www-mobile	Mobile Technology (e.g. smartphone or tablet app/widget, quick response (QR) codes, mobile websites)
www-soc-med	Internet Social Media (e.g. social networking, microblog/blog, online community, wiki)
www-video	Internet Video
www-website	Internet Website

7c. Dissemination/Publication Date – The date of the initial dissemination/publication of the promotional labeling piece or advertisement. Use drop-down calendar or MM/DD/YYYY format.

7d. Material ID Code – The applicant's identification code or other designation of the specific promotional material.

7e. Material Description – The applicant's description of the specific promotional material.

7f. Comments – Include any information that is pertinent to the dissemination method of the materials. Also include a comment if a piece is meant to be disseminated exclusively with other pieces and indicate the accompanying pieces.

8. Applicant (or Agent's) Return Address, including the country.

9 a, b, & c. Telephone Number, FAX Number, and Email Address – The telephone and facsimile numbers and email address of the responsible official or agent.

10. Typed Name and Title of Responsible Official or Agent – The individual responsible for responding to any inquires regarding the 2253 submission.

11. Signature of Responsible Official or Agent

12. Date – Date of signature. Use drop-down calendar or MM/DD/YYYY format.

13. Biological products – For CBER products only, draft or final.

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NOTE:

Forward Form and attachments for drugs and therapeutic biologic products to: Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, MD 20705

Forward Form and attachments for biologics to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Avenue, Building 71, Room G112, Silver Spring, MD 20993-0002