Guidance for Industry

Providing Regulatory Submissions in Electronic Format —

Prescription Drug Advertising and Promotional Labeling

Draft Guidance

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability published in the *Federal Register*.

For questions regarding this draft document contact (CDER) Warren Rumble, 301-827-2831, or (CBER) Michael Fauntleroy, 301-827-5101.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

January 2001
IT

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Additional copies are available from:

Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
5600 Fishers Lane
Rockville, MD 20857
(Tel) 301-827-4573
(Internet) http://www.fda.gov/cder/guidance/index.htm

or

Office of Communication, Training and
Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Rockville, MD 20852-1448
Internet: http://www.fda.gov/cber/guidelines.htm.
Fax: 1-888-CBERFAX or 301-827-3844
Mail: the Voice Information System at 800-835-4709 or 301-827-1800

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This draft guidance, when finalized, will represent the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. INTRODUCTION

This is one in a series of guidance documents intended to assist applicants making regulatory submissions in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). This specific guidance discusses issues related to the electronic submission of advertising and promotional labeling materials for prescription drug and biological products, including launch materials. In some cases, guidance differs from CDER to CBER because of differences in the procedures and computer infrastructure in the centers. We will work to minimize these differences wherever possible. Agency guidance documents on electronic submissions will be updated regularly to reflect the evolving nature of the technology and the experience of those using this technology.

For a list of guidances that are under development on electronic submissions, see *Regulatory Submissions in Electronic Format — General Considerations* (January 1999). The General Considerations guidance also addresses issues, such as file formats, media, and submission procedures, that are common to all submission types.

II. GENERAL ISSUES

A. Scope

This guidance addresses the submission of the following materials.

[1] This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

1. Advertisements and promotional labeling submitted under 21 CFR 314.81(b)(3)(i) or 601.12(f)(4) as part of the postmarketing reporting regulations for approved applications with either Forms FDA 2253 (CDER or CBER) or 2567 (CBER).[2] These regulations provide general requirements for submitting advertising and promotional labeling material to CDER and CBER at the time of publication of an advertisement, and at the time of initial dissemination of promotional labeling.

2. Proposed advertisements and promotional labeling planned for use in a medical product's launch campaign voluntarily submitted as a request for comment and other proposed materials voluntarily submitted with a request for comment

    - CBER — All submissions to CBER should be accompanied by Part I of either Form 2567 or 2253, as appropriate.

    - CDER — Materials submitted voluntarily to CDER should not be accompanied by Form 2567 or 2253.

3. Advertisements and promotional labeling submitted under the requirements of 21 CFR 314.550 and 21 CFR 601.45 as part of the accelerated approval requirements and restricted distribution for drug and biological products[3]

    - CBER - Materials should be submitted to CBER with either Form FDA 2253 or 2567 (Part I or II), as appropriate, to aid in tracking.

    - CDER - After publishing the advertising or disseminating the promotional labeling, these promotional materials should be submitted as described in A. 1. above.

4. Requests for comment on materials for the development of evidence to support future advertising or promotional labeling claims (i.e., health-related quality of life outcomes)

5. Submissions under 21 CFR Part 99[4] of materials regarding the dissemination of information on unapproved/new uses for drugs, biological products and devices

B. Electronic Signatures

The Agency is developing procedures for archiving documents with electronic signatures. Until those procedures are in place, we will not be able to accept electronic signatures in place of hand

[2] Forms FDA 2253 and 2567 can be found at http://aosweb.psc.dhhs.gov/forms/fdaforms.htm

[3] In March 1999, the Agency issued a draft guidance titled *Accelerated Approval Products — Submission of Promotional Materials* (March1999), which will reflect the Agency's views on this topic, once it has been finalized.

[4] The Food and Drug Administration Modernization Act of 1997, section 401.

written signatures. This means that for documents requiring a handwritten signature (e.g., certifications), you should include a paper version with the hand written signature along with the electronic version.

C. Mixed Submissions — Electronic and Paper

If you decide to submit advertisements and promotional labeling materials in electronic format, the entire submission should be in electronic format. We prefer that all subsequent submissions related to the initial submission be in electronic format.

D. General Information on Logistics of Sending Electronic Submissions

You can find general information on the logistics of sending electronic submissions in guidance for industry, *Providing Regulatory Submissions in Electronic Format – General Considerations* (January 1999).

III. ORGANIZING THE MAIN FOLDER

All documents should be placed in a main folder using the NDA, IND, or BLA number (e.g., N123456, I123456, or B123456, respectively) as the folder name.

A. Folders

Inside the main folder, you should include two folders, *promo* and *refs*, to organize the files supporting the submission. The promotional material(s) and supporting reference(s) should be placed in the *promo* and *refs* folders, respectively.

B. Optional Cover Letter

If you decide you would like to provide a cover letter with additional information, such as the materials needing priority reviews and a technology point of contact, the cover letter should be provided as a portable document format (PDF) file named *cover.pdf* inside the main folder.

This cover letter is not a substitute for requested FDA forms for CBER. For example, if you wish to voluntarily submit advertising and promotional labeling material for comment to CBER, you should continue to submit Part I of FDA Forms 2567 or 2253 in addition to a cover letter.

C. Forms FDA 2253 and 2567

When submitting Form FDA 2253 or 2567, you should provide it as a PDF file named *2253.pdf* or *2567.pdf* inside the main folder. Until the Agency is prepared to receive electronic signatures, a signed paper Form FDA 2253 or 2567 should accompany the promotional material submitted under 21 CFR 314.81(b)(3).

D. Current Labeling Text

You should provide a copy of the currently used labeling text as a PDF file named *current.pdf* in the main folder. The currently used labeling text may differ from the most recent approved labeling text under the provisions of 21 CFR 314.70 and 21 CFR 314.81(b)(2). In the case of submissions provided prior to approval, you should submit the most recent draft labeling text.

The labeling text is the content and format of labeling as defined in 21 CRF 201.56 and 201.57 and includes all text, tables, and figures used in the package insert.[5] You should generate the PDF file for the labeling text from electronic source documents and not from scanned material.

E. Table of Contents

Inside the main folder, you should provide a table of contents for the submission named *toc.pdf*. You should supply a hypertext link to the corresponding file. For an example, see Table 1.

Table 1: Example Table of Contents for a Submission

Description	**Folder/file name**
Form FDA 2253	Main/2253.pdf
Cover letter	Main/cover.pdf
Current labeling	Main/current.pdf
Promotional material	Promo
List promotional material starting here	
References	Refs
List references starting here	

F. Roadmap.pdf File (CBER only)

The root directory of the electronic submission should contain a *roadmap.pdf* file to orient reviewers to the original submission of promotional materials as well as any subsequent information.

The *roadmap.pdf* file should contain a hypertext link to the submission's main table of contents. The *roadmap* should be updated and resubmitted as additional information is supplied in support of the prescription drug advertising or promotional labeling submission.

The roadmap file should not contribute in any way to the content of your submission. It is a map, intended to facilitate navigation through the contents of the submission. The

[5] See guidance for industry, *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999) and *Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format-Biologics Marketing Applications* (November 1999) for additional details on providing the currently used labeling text.

submission's *roadmap.pdf* file should be easily updated or modified using the *Replace file* command under the *Document* menu option in Adobe Acrobat. This function will automatically replace the hypertext links to previously submitted information, leaving only the task of creating new hypertext links to the newly submitted information.

In addition to providing a navigable guide to your submission, the *roadmap.pdf* file should include the sponsor's submission date in the DD-MM-YYYY format (e.g., 01-Jan-1999). The contents of the submission and of its subsequent amendments should be briefly described in a roadmap.pdf table.

IV. ORGANIZING THE ELECTRONIC SUBMISSION

The submission should include the promotional materials and supporting documents. The guidance for providing these items in electronic format follows.

A. Promotional materials

You should provide each promotional piece as an individual PDF file. For three-dimensional objects, you should provide a digital image of the object in sufficient detail to allow us to review the promotional material. In addition, you should provide information adequate to determine the size of the object (i.e., point size, dimensions). You should place all promotional material PDF files in the folder named *promo*.

B. References

You should provide each reference as an individual PDF file and highlight the sections of the full reference that you refer to in the promotional material. You should place these files in the folder named *refs.* When ever possible, you should generate the PDF files from electronic source documents and not from scanned material.

When a reference is used to support a claim in proposed promotional materials voluntarily submitted for advisory opinion or Agency comment, you should provide a hypertext link to the page of the reference or labeling that contains the supporting information.

For promotional materials submitted as part of the postmarketing reporting requirements, you can also provide hypertext links to references or labeling.