4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1163]

Providing Regulatory Submissions in Electronic and Non-Electronic Format--Promotional Labeling and Advertising Materials for Human Prescription Drugs, Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic and Non-Electronic Format--Promotional Labeling and Advertising Materials for Human Prescription Drugs." This draft guidance explains how manufacturers, packers, and distributors (firms) that may either be the applicant or acting on behalf of the applicant, should make submissions pertaining to promotional materials for human prescription drugs and biologic products ("drugs") to the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) and the Advertising and Promotional Labeling Branch (APLB) in the Center for Biologics Evaluation and Research (CBER). This draft guidance describes the various types of submissions of promotional materials and general considerations for submissions. In addition, this draft guidance discusses the specific aspects of submission of promotional materials using module 1 of the electronic Common Technical Document (eCTD) using version 3.3 or higher of

the us-regional-backbone file. This guidance does not address the more general requirements for a valid electronic submission using eCTD or the specifications for module 1 of the eCTD. This guidance contains both binding and nonbinding provisions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments on the proposed collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Marci Kiester, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3368, Silver Spring, MD 20993-0002, 301-796-1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic and Non-Electronic Format--Promotional Labeling and Advertising Materials for Human Prescription Drugs." This draft guidance is intended to be used in conjunction with the draft guidance for industry "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications"[1] (eCTD Revised Draft Guidance) and in conjunction with the specification to industry "The eCTD Backbone Files Specification for Module 1 Version 2.3."[2]

This draft guidance describes various types of regulatory submissions of promotional materials that firms submit to CDER and CBER and general considerations for such submissions. For example, the draft guidance describes the various types of voluntary submissions (e.g., launch and non-launch voluntary submissions of draft promotional materials

[1] The draft guidance for industry is available on the FDA eCTD Web page at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf.

[2] The specification for industry is available on the FDA eCTD Module 1 Web page at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm.

for advisory comments) and required submissions of promotional labeling and advertising materials (e.g., fulfillment of the regulatory requirements for postmarketing submissions of promotional materials and submission of promotional materials for accelerated approval products). In addition, this draft guidance discusses specific aspects of the content and format for submitting promotional materials in paper hard copy and electronic format, including how to submit promotional materials electronically in module 1 of the eCTD using version 3.3 or higher of the us-regional-backbone file. This draft guidance provides recommendations for what to include with each type of submission and the number of copies to include if it is a paper submission. This draft guidance provides recommendations for presentation considerations such as appearance, layout, format, and visible impression of promotional materials submitted for all promotional submission types.

This draft guidance also provides instructions on how to submit promotional labeling and advertising materials to FDA electronically in eCTD format. It explains that for submissions of promotional materials that fall within the ambit of section 745A(a) of the FD&C Act, as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), such submissions must be made in the electronic format specified by FDA in this guidance and the eCTD Revised Draft Guidance, beginning no earlier than 24 months after this guidance is finalized. Specifically, (1) postmarketing submissions of promotional materials using Form FDA 2253 (required by 21 CFR 314.81(b)(3)(i) and 21 CFR 601.12(f)(4), and (2) submissions of promotional materials for accelerated approval products (required by FD&C Act section 506(c)(2)(B) (21 U.S.C. 356(c)(2)(B)), and §§ 314.550 and 601.45) and other products where such submissions are required for approval, fall within the scope of section 745A(a) and are, therefore, subject to the mandatory electronic submission requirement. When the mandatory

electronic submission requirement takes effect for these types of submissions, they will only be accepted by CDER in eCTD format using version 3.3 or higher of the us-regional-backbone file. CBER will be able to accept eCTD submissions using previous versions of the us-regional-backbone file until 24 months after publication of the final version of this guidance. The draft guidance also provides that, while only promotional submissions that fall under section 745A(a) will be required to be submitted electronically no sooner than 24 months after this guidance is finalized, firms may choose--and are strongly encouraged--to submit electronically the other types of promotional submissions discussed in this guidance.

This draft guidance is being issued under section 745A(a) of the FD&C Act, which explicitly authorizes FDA to implement the statutory electronic submission requirement for certain types of submissions by specifying the format for such submissions in guidance. Accordingly, to the extent that the draft guidance provides such requirements under section 745A(a), it is not subject to the usual restrictions in FDA's good guidance practices regulation (21 CFR 10.115). However, to the extent that the draft guidance includes provisions regarding submission of promotional materials that do not pertain to the electronic format requirements for submissions under section 745A(a), it will represent the Agency's current thinking on the submission of promotional materials and will not create or confer any rights for or on any person or bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44

U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Providing Regulatory Submissions in Electronic and Non-Electronic Format--Promotional Labeling and Advertising Materials for Human Prescription Drugs

Description of Respondents: Respondents to this collection of information are firms who make regulatory submissions pertaining to promotional materials for human prescription drug and biologic products to OPDP and APLB.

Burden Estimate: The draft guidance pertains to regulatory submissions of promotional materials. The draft guidance describes the types of submissions of promotional materials,

general considerations for submissions, and certain considerations for how to submit promotional materials electronically and in hard copy.

The draft guidance includes recommendations for when sponsors make submissions to OPDP or APLB. These recommendations include the types of documents that generally should be included (e.g., correspondence describing the type of submission) for promotional labeling submitted for advisory comments, resubmissions, general correspondence, amendments, withdrawal requests, responses to untitled letters or warning letters, responses to information requests, reference documents, and complaints.

For promotional labeling submitted for advisory comments, including resubmissions, a submission generally includes correspondence stating that it is a request for advisory comments, a clean version of the draft promotional materials, an annotated copy of the promotional materials, and the most current FDA-approved prescribing information (PI); if applicable, a submission also includes the FDA-approved patient labeling or Medication Guide with annotations cross-referenced to the proposed promotional materials and annotated references to support product and disease or epidemiology claims not contained in the PI cross-referenced to the promotional material. Amendments should be submitted if the previous submission to FDA is missing one or more promotional materials. Amendments should include correspondence stating it is an amendment and include the accompanying materials that were previously missing, an annotated copy of the promotional materials that were omitted from a previous submission to FDA, the FDA-approved patient labeling or Medication Guide with annotations cross-referenced to the proposed promotional materials, and annotated references to support product and disease or epidemiology claims not contained in the PI cross-referenced to the promotional material.

General correspondence submissions and submissions requesting to withdraw a previous submission to FDA include correspondence stating the purpose of the submission.

Responses to untitled or warning letter submissions include correspondence stating that it is a response to an untitled or warning letter, and include the firm's initial or subsequent responses and the corrective piece(s), if applicable.

Responses to information request submissions include the firm's response to the questions and issues raised in FDA's letter of inquiry, including any materials that FDA has requested.

Reference document submissions include correspondence stating that it is a reference document submission and the specific information regarding what is in the submission along with the annotated references, annotated promotional materials, and/or annotated labeling.

Promotional labeling submitted for advisory comments, including resubmissions and amendments; general correspondence; requests to withdraw a previous submission; responses to untitled or warning letters; responses to information requests; and reference documents can be submitted in paper or electronic form, and the burden estimates for these submissions in table 1 apply to both paper and electronic form.

Complaints include correspondence stating that it is a complaint and supporting information or documentation, if available. Complaints are not accepted in electronic form and should be submitted as paper hard copies. The burden estimate for complaints in table 1 thus applies to paper hard copies only.

The draft guidance also describes the number of paper hard copies that should be sent to OPDP and APLB for each submission type (if applicable).

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Type of Submission	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours
Promotional labeling submitted for advisory comments, including resubmissions and amendments	199	2.5	499	50	24,950
General correspondence submitted to FDA	200	2.5	500	2	1,000
Requests to withdraw a previous submission to FDA	6	1	6	2	12
Responses to untitled or warning letters	26	2	52	12	624
Responses to information requests	4	1.5	6	12	72
Reference documents	7	1	7	12	84
Complaints submitted to OPDP	60	1	60	12	720
Total					27,462

This draft guidance also refers to previously approved collections of information found in FDA regulations and collections of information that are currently under OMB review. The collections of information in 21 CFR 202.1, including requests for advisory comments, resubmissions, and amendments for advertisements, have been approved under OMB control number 0910-0686; the collections of information in 21 CFR 601.45 (presubmission of promotional materials for accelerated approval products under part 601) have been approved under OMB control number 0910-0338; the collections of information for FDA Form 2253 and the presubmission of promotional materials for accelerated approval products under part 314 have been approved under OMB control number 0910-0001. FDA has also published in the Federal Register a 60-day notice soliciting public comments on the collections of information that result from the submission of television advertisements under section 503C of the FD&C Act (21 U.S.C. 353c) (77 FR 14811, March 13, 2012). These burden estimates do not change as a result of this guidance. This is because new burdens for establishing the means for submitting

materials in electronic form to comply with this guidance would be negated by the savings in burden from not having to print out the materials and mail them to FDA.

Some firms may incur costs associated with upgrading technology or changing the method of submitting information to FDA, and these have been described in the Federal Register notice for the revised draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications" (79 FR 43494, July 25, 2014).

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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