4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Regulatory Submissions in Electronic and Non-Electronic Format--Promotional Labeling and Advertising Materials for Human Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Providing Regulatory Submissions in Electronic and Non-Electronic Format--Promotional Labeling and Advertising Materials for Human Prescription Drugs." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910-NEW

This information collection request supports recommendations found in the Agency guidance document entitled, "Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs." The guidance document outlines the requirements and recommendations for manufacturers, packers, and distributors (firms) that may either be the applicant or acting on behalf of the applicant, to make submissions pertaining to promotional materials for human prescription drugs ("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). References to "drugs" in the guidance also include human biological products that fall within the definition of "drug" under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g)).

The guidance describes the various types of submissions of promotional materials and general considerations for submissions. The 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. The guidance does not address the more general requirements for a valid electronic submission using eCTD or the specifications for module 1 of the eCTD. The guidance contains both binding and nonbinding provisions. The provisions that are binding implement section 745A(a) of the FD&C Act (21 U.S.C. 379k-1(a)), which requires that certain submissions be submitted in electronic format specified by FDA, beginning no earlier than 24 months after FDA issues a final guidance specifying such electronic submission format.

The 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. 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 or if an incorrect document file was included with a submission in eCTD format. 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 copies. The burden estimate for complaints in table 1 thus applies to paper copies only.

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

The guidance provides recommendations for presentation considerations such as appearance, layout, format, and visible impression of promotional materials submitted for all promotional submission types.

The 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 (21 U.S.C. 379k-1(a)), 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 the guidance, beginning no earlier than 24 months after the guidance is finalized. Specifically, (1) postmarketing submissions of promotional materials using Form FDA 2253 (required by 21 CFR 314.81(b)(3)(i) and 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 21 CFR 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 be accepted by CDER only 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 guidance. The 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 the guidance is

finalized, firms are strongly encouraged, but not required, to submit electronically the other types of promotional submissions discussed in the guidance.

In the *Federal Register* of April 22, 2015 (80 FR 22529), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received requesting clarification on the submission of annotated versions of promotional materials for Form FDA 2253 submissions. We appreciate the comment and have revised the guidance to further clarify that annotated versions of promotional materials are encouraged, not required. The guidance was also revised to encourage the submission of a CD copy of paper submissions and burden estimates have been updated accordingly. Any increase in burden is expected to be nominal.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

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	76	13	1,024	51	52,224
General correspondence submitted to FDA	84	4	359	3	1,077
Requests to withdraw a previous submission to FDA	15	1	22	3	66
Responses to untitled or warning letters	7	2	13	13	169
Responses to information requests	6	1	3	13	39
Reference documents	7	2	14	13	182
Complaints submitted to FDA	82	1	117	13	1,521
Total					55,278

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on our experience with the submission of labeling materials for human prescription drugs. Because this is a new collection of information, we are specifically

interested in receiving comments from respondents to the information collection regarding our burden estimate.

Dated: March 29, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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