4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0256 (formerly 2007D-0089)]

Agency Information Collection Activities: Proposed Collection; Comment Request; Draft Guidance for Industry and Review Staff on Target Product Profile--A Strategic Development Process Tool

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in the draft guidance for industry and review staff entitled "Target Product Profile--A Strategic Development Process Tool."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2007-D-0256

(formerly 2007D-0089) for "Agency Information Collection Activities: Proposed Collection; Comment Request; Draft Guidance for Industry and Review Staff on Target Product Profile--A Strategic Development Process Tool." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the 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, in the Federal Register of March 30, 2007 (72 FR 15141), FDA published a notice of availability of the draft guidance document with a 60-day notice requesting public comment on the collection of information. In response to a request by OMB, FDA is republishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (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.

The draft guidance is intended to provide sponsors and FDA review staff with information regarding target product profiles (TPPs). A TPP can be prepared by a sponsor and then shared voluntarily with the appropriate FDA review staff to facilitate communication regarding a particular drug development program. A Clinical Development Working Group recommended use of a template that provides a summary of drug labeling concepts to focus discussions and aid in the understanding between sponsors and FDA. The resulting TPP is a format for a summary of a drug development program described in terms of labeling concepts. With the TPP, a sponsor specifies the labeling concepts that are the goals of the drug development program, documents the specific studies that are intended to support the labeling concepts, and then uses the TPP to assist in a constructive dialogue with FDA. The draft guidance describes the purpose of a TPP, its advantages, and its optimal use. It also provides information on how to complete a TPP and relates case studies that demonstrate a TPP's usefulness.

Sponsors are not required to submit a TPP. The TPP does not represent an implicit or explicit obligation on the sponsor's part to pursue all stated goals. Submission of a TPP summary does not constrain the sponsor to submit draft labeling in a new drug application (NDA) or biologics license application (BLA) that is identical to the TPP. The TPP is part of the proprietary investigational new drug application (IND) file.

The TPP is organized according to the key sections of the drug labeling and links drug development activities to specific concepts intended for inclusion in the drug labeling. The TPP is not a long summary. Generally, the TPP is shorter than the ultimate annotated draft labeling because it captures only a summary of the drug development activities and labeling concepts. Early TPPs can be brief depending on the status of the drug's development process.

The Target Product Profile Template in Appendix C of the draft guidance details the suggested information to be included in each section of the TPP. The TPP includes information from each discipline comprising an NDA/BLA. Within each discipline, the TPP briefly summarizes the specific studies that will supply the evidence for each conclusion that is a labeling concept. A TPP is organized according to key sections in the drug's labeling. Typical key sections are:

- Indications and Usage
- Dosage and Administration
- Dosage Forms and Strengths
- Contraindications
- Warnings and Precautions
- Adverse Reactions
- Drug Interactions
- Use in Specific Populations
- Drug Abuse and Dependence
- Overdosage
- Description
- Clinical Pharmacology

- Nonclinical Toxicology
- Clinical Studies
- References
- How Supplied/Storage and Handling
- Patient Counseling Information

Description of Respondents: Sponsors of applications seeking FDA approval to perform clinical investigations of a human drug before applying for marketing approval of the drug from FDA.

Burden Estimate: FDA estimates that sponsors of approximately 10 percent of the number of active INDs submitted to FDA annually would prepare and submit TPPs. This would equal approximately 132 TPPs per year. Based on data received from the Pharmaceutical Research and Manufacturers of America, we estimate that approximately 20 sponsors would submit TPPs and that each TPP would take approximately 20 hours to prepare and submit to FDA. Based on the previous methodology and assumptions, the following table provides an estimate of the annual reporting burden for the voluntary submission of TPPs under the draft guidance. FDA requests comments on this analysis of information collection burdens.

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

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Target Product Profiles (TPPs)	20	6.6	132	20	2,640

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

Dated: December 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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