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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Review Staff on Target Product Profile--A Strategic Development Process Tool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 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 All comments should be identified with the OMB control number 0910-NEW and title "Draft Guidance for Industry and Review Staff on Target Product Profile--A Strategic Development Process Tool." 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.

Guidance for Industry and Review Staff on Target Product Profile--A Strategic Development Process Tool

OMB Control Number 0910-NEW

This information collection request supports the above-captioned Agency guidance. The draft guidance is intended to provide sponsors and FDA review staff with information regarding target product profiles (TPPs).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. The TPP is based on 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

In the *Federal Register* of January 5, 2016 (81 FR 240), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of the information collection as follows:

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

Guidance Recommendations	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
TPPs	20	6.6	132	20	2,640

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

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. According to our records, this equals 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 submission would take approximately 20 hours to prepare. This information is reflected in table 1.

Dated: November 3, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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