The study will involve 45 respondents and take approximately 45 minutes each to complete. These estimates are based on FDA's experience with consumer research.

Dated: March 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–1577 Filed 3–29–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0089]

Draft Guidance for Industry and Review Staff on Target Product Profile—A Strategic Development Process Tool; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and review staff entitled ''Target Product Profile—A Strategic Development Process Tool.'' The purpose of this guidance is to inform sponsors and the review staff in the Center for Drug Evaluation and Research (CDER) of the availability and potential usefulness of a target product profile (TPP). 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. This draft guidance describes the purposes of a TPP, provides guidance on how to complete a TPP, makes suggestions on how to best use a TPP, and relates case studies that demonstrate the potential usefulness of a TPP.

DATES: Submit written or electronic comments on the draft guidance and/or on the collection of information by May 29, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance and/or on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jeanne M. Delasko, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6474, Silver Spring, MD 20993–0002, 301–796–0900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Target Product Profile—A Strategic Development Process Tool.'' In 1997, a Clinical Development Working Group composed of representatives from FDA and pharmaceutical sponsors began discussions on ways to improve sponsor and FDA interactions in the drug development process. The 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.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on target product profiles. 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.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), 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 below.

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 on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry and Review Staff: Target Product Profile—A Strategic Development Process Tool.

Description: The draft guidance is intended to provide sponsors and FDA review staff with information regarding 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 since 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 as follows:

- 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 chart 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	Hours 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed continuing information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the National Flood Insurance Program—Mortgage Portfolio Protection Program (MPPP) that is a mechanism used by lending institutions mortgage servicing companies, and others servicing mortgage loan portfolios to bring the mortgage loan portfolios into compliance with the flood insurance purchase requirements of the Flood Disaster Protection Act of 1973, as amended.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), authorized by the National Flood Insurance Act of 1968, Public Law 90–448, and expanded by the Flood Disaster Protection Act of 1973, Public Law 93–234, as amended, provides federally backed flood insurance for buildings exposed to flood risk. In accordance with Public Law 93–234 the purchase of flood insurance is mandatory when Federal and federally related assistance is being provided for acquisition or construction of buildings located or to be located within FEMA identified Special Flood Hazard Areas of communities which are participating in the program.

Collection of Information

Title: National Flood Insurance Program—Mortgage Portfolio Protection Program (MPPP).

Type of Information Collection: Extension, without change, of a currently approved collection.

OMB Number: 1660–0086.

Form Numbers: None.

Abstract: The MPPP is a mechanism used by lending institutions mortgage servicing companies, and others servicing mortgage loan portfolios to bring the mortgage loan portfolios into