DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0105]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mental Models Study of Food Bioterrorism Risk Awareness

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 information collection provisions of the mental models study of food bioterrorism risk awareness.

DATES: Submit written or electronic comments on the collection of information by May 29, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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, 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.

Mental Models Study of Food Bioterrorism Risk Awareness

The proposed information collection will help FDA protect the public from food bioterrorism by preparing the agency to take appropriate action in the event of a crisis. Under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, FDA has authority to act to protect the safety of the nation's food supply. Under title 42 of the Public Health Service Act (1944), FDA has authority to act to protect the public health. In addition, title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188), FDA has authority to act to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.

FDA has crafted and disseminated messages intended to raise the awareness of state and local government agency and industry representatives regarding food defense issues and preparedness, but FDA does not currently have similar initiatives for consumers. Extensive research exists in disaster preparedness and in effective communication to the public of risk or crisis information by government or non-government entities. However, additional research is needed to help FDA design communications that will increase consumer awareness of the potential for food bioterrorism and help consumers to make good decisions in the event of a food bioterrorism emergency.

The project will use ''mental modeling,'' a qualitative research method wherein the decision-making processes of a group of consumer respondents (described in the next paragraph) concerning food bioterrorism are modeled and compared to a model based on expert knowledge and experience in food bioterrorism. The information will be collected via a telephone interview concerning the factors that influence the perceptions and motivations related to the threat of food bioterrorism. A comparison between expert and consumer models based on the collected information may identify ''consequential knowledge gaps'' that can be redressed through messages or information campaigns designed by FDA.

Description of Respondents: Respondents will be adult parents over the age of 18 who have at least one child age 4 to 13 residing in the home at least half-time. The sample will be divided by gender.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
45	1	1	.75	33.75

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

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]

BILLING CODE 4160–01–S

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.