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The Target Product Profile Template in Appendix C of the draft guidance details the suggested information to be included in each section of the TPP.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the following chart provides an estimate of the annual reporting burden for the voluntary submission of TPPs under the draft guidance.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.

[FR Doc. E7–5949 Filed 3–29–07; 8:45 am]

BILLING CODE 4160–01–S

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

compliance with the flood insurance purchase requirements of the Flood Disaster Protection Act of 1973, as amended. Implementation of various requirements of the MPPP should result in mortgagors, following receipt of notification of the need for flood insurance, showing evidence of such a policy or purchasing the necessary insurance through their local insurance agent or appropriate Write Your Own (WYO) Company. It is intended that NFIP policies be written under the MPPP only as a last resort, and only on mortgages whose mortgagors have failed to respond to the various notifications required by the Program. The requirements of the MPPP are contained in 44 CFR 62.23(l)(1).

Affected Public: Individuals and households; businesses or other for-profit; not-for-profit institutions; farms; Federal agencies or employees; and State, local or tribal governments.

Estimated Total Annual Burden Hours: 2,386 hours.

ANNUAL BURDEN HOURS

Project/activity (survey, form(s), focus group, worksheet, etc.)	Number of respondents	Frequency of responses	Burden hours per respondent	Annual responses	Total annual burden hours
	(A)	(B)	(C)	(D) = (A × B)	(E) = (C × D)
WYO—Lender/Services Coordination	22	1	.5	22	11
Lenders/Mortgagors Service Coordination	250	1	.5	250	125
WYO Company Policy Issuance	6000	1	.25	6000	1500
WYO Company (New Program Entrant Insurance Company)	1	1	*750	1	750
Total	6,273				2,386

*The 750 burden hours per respondent is the amount of time it takes a new program entrant (insurance company) to prepare, train, and compile various needed information.

Estimated Cost: $107,350.

Comments: Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. Comments must be submitted on or before May 29, 2007.

ADDRESSES: Interested persons should submit written comments to Chief, Records Management and Privacy, Information Resources Management Branch, Information Technology Services Division, Federal Emergency Management Agency, 500 C Street, SW., Room 609, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Contact Edward Connor, Deputy Director of Insurance, Mitigation Division, Federal Emergency Management Agency, Department of Homeland Security, 202–646–3429, *edward.connor@dhs.gov*, for additional information. You may contact the Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646–3347or email address: *FEMA-Information-Collections@dhs.gov*.

Dated: March 26, 2007.

John A. Sharetts-Sullivan,

Chief, Records Management and Privacy, Information Resources Management Branch, Information Technology Services Division, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E7–5910 Filed 3–29–07; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Immigration and Customs Enforcement

Agency Information Collection Activities: Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review; Form G–146, Nonimmigrant Checkout Letter; OMB Control No. 1653–0020.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until May 29, 2007.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Ricardo Lemus, Chief, Records Management Branch, Bureau of Immigration and Customs Enforcement, 425 I Street, NW., Room 1122, Washington, DC 20536; (202) 514–3211.

Comments are encouraged and will be accepted for sixty days until May 29, 2007. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.