procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

The record of the total annual payments made to each physician or supplier is derived from the individual Medicare bill payments.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 02–15009 Filed 6–13–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0590]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Salmonella Discovery System Pilot Study

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 15, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Salmonella Discovery System Pilot Study

FDA's Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Informatics and Computational Safety Analysis Staff intends to conduct a *Salmonella* Discovery System Pilot Study (the pilot study). The primary goal of the pilot study is to construct and execute a mutually beneficial process by which FDA and pharmaceutical companies can share information based on their proprietary toxicology study data and thereby expand their own knowledge databases. This process will be designed and conducted using procedures that do not compromise the identity and chemical structures of the individual collaborator's proprietary chemicals.

The three major objectives of the pilot study are to:

- Build a joint and comprehensive FDA/pharmaceutical industry database for compounds tested in the *Salmonella typhimurium* reverse mutagenicity assay;
- Use these data to construct a new enhanced *Salmonella t.* mutagenicity assay database module for the MultiCASE quantitative structure activity relationship software program; and
- Employ the recently developed MultiCASE expert system (MCASE–ES) to predict the mutagenic response, mutagenic potency, and mechanism of mutagenesis of test chemicals in *Salmonella t.*

The pilot study will be a joint venture designed to maximize the benefits and minimize the risks to all collaborators. FDA intends to send letters to companies that have purchased either MultiCASE or CASETOXII software programs to invite them to become a collaborator in the project.

FDA intends to request that each collaborator submit the following data electronically: (1) Test compound chemical structures; and (2) assay data, identifying the type of *Salmonella* mutagenicity assay used in the studies, the source and concentration of any exogenous activation system used, and the average number of revertants/plate for the negative control, positive control, and each of the test compound treatment groups. Although there is no minimum requirement for the number of test compounds to be submitted to FDA, the agency would expect to receive at least 200 compounds from each collaborator. Each company will be able to identify its own compounds in the resulting discovery system, and the more data submitted, the greater the coverage will be for each company's molecular universe.

FDA intends to act as the broker for the pilot study and will be responsible for the confidentiality and integrity of each collaborator's proprietary data. The number of compounds in the database module will depend upon the number of collaborators and the size of the data sets they contribute to the pilot study. After the enhanced *Salmonella* discovery system has been constructed and tested, FDA intends to custom prepare individual discovery systems for each collaborator.

The anticipated benefits to collaborators include:

- Receipt of a new expanded *Salmonella in silico* discovery tool at no cost;
- Access to proprietary molecular fragment data derived from *Salmonella t.* mutagenicity studies from FDA and other collaborator archives;
- Comprehensive lists of molecular structural alerts correlated with mutagenicity in *Salmonella t.*, including previously uncharacterized alerts derived from heretofore inaccessible undeveloped lead pharmaceutical test data; and
- A *Salmonella* discovery system which should provide high coverage and high predictive performance for organic chemicals in each company's combinatorial and lead chemical data sets.

The *Salmonella* discovery system provided by FDA will be compatible with each company's current MCASE software program currently v. 3.46 and will supplement current *Salmonella* modules purchased from MultiCASE, Inc.

Participation in this pilot study will be voluntary. FDA estimates that approximately 12 companies will participate, and that it will take each company approximately 8 hours to compile the information from electronic archives and submit the requested data and information.

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
12	1	12	8	96

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

In the **Federal Register** of January 28, 2002 (67 FR 3902), the agency requested comments on the proposed collections of information. No comments were received.

Dated: June 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–15002 Filed 6–13–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0054]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Labeling Requirements for Color Additives (Other Than Hair Dyes) and Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 15, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Labeling Requirements for Color Additives (Other Than Hair Dyes)—21 CFR 70.25 and Petitions—21 CFR 71.1 (OMB Control Number 0910–0185)—Extension

Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or unless the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Color additive petitions are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 (21 CFR 71.1) specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use.

FDA scientific personnel review color additive petitions to ensure that the intended use of the color additive in or on food, drugs, cosmetics, and medical devices is suitable and safe. Color additive petitions were specifically provided for by Congress when it enacted the Color Additive Amendments of 1960 (Public Law 94–295). If FDA stopped accepting color additive petitions or stopped requiring them to contain the information specified in § 71.1, there would be no way to bring new uses of listed color additives or new color additives to market. FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

Respondents are businesses engaged in the manufacture or sale of color additives for use in food, drugs, cosmetics, or medical devices.

In the **Federal Register** of February 28, 2002 (67 FR 9297), the agency requested comments on the proposed collection of information. No comments were received that pertained to this collection of information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating and Maintenance Costs	Total Hours
70.25	0	1	0	0	0	0
71.1	3	1	3	2,000	$8,600	6,000
Total						6,000

[1] There are no capital costs associated with this collection of information.

This estimate is based on the number of new color additive petitions received in fiscal year 2000 and the total hours expended by petitioners to prepare the petitions. Although the burden varies with the type of petition submitted, a color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself. Because labeling requirements under § 70.25 for a particular color additive involve information required as part of the color additive petition safety review process, the estimate for the number of respondents is the same for § 70.25 as for § 71.1, and the burden hours for labeling are included in the estimate for § 71.1.

Color additives are subjected to payment of fees for the petitioning