ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV–E State Plan	12	1	15	180

Estimated Total Annual Burden Hours: 180.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 5, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–4805 Filed 3–12–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0150]

Draft Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims.'' This draft guidance is intended to assist applicants in developing labeling for cardiovascular outcome claims for drugs that are indicated to treat hypertension. Because blood pressure control is well established as beneficial in preventing serious cardiovascular events, FDA believes that the appropriate use of these drugs can be encouraged by making the connection between lower blood pressure and improved cardiovascular outcomes more explicit in labeling. This draft guidance is intended to recommend standard labeling for antihypertensive drugs except where differences are clearly supported by clinical data.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance byMay 12, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Devi Kozeli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4183, Silver Spring, MD 20993–0002, 301–796–1128.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims.'' On June 15, 2005, the Cardiovascular and Renal Drugs Advisory Committee met in open public session to discuss class labeling for cardiovascular outcome claims for drugs that are indicated to treat hypertension. With few exceptions, current labeling for antihypertensive drug products only includes the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction. However, blood pressure control is well established as beneficial in preventing serious cardiovascular events, and inadequate treatment of hypertension is acknowledged as a significant public health problem. The committee voiced a broad consensus in favor of labeling changes to describe briefly the clinical benefits related to cardiovascular outcomes expected from lowering blood pressure with any antihypertensive drug. The labeling proposed in this draft guidance is consistent with the advisory committee's recommendations.

This draft guidance is being made available to afford the public the opportunity to comment on both the intent of the labeling revisions and the specific proposed language. This draft guidance is intended to recommend standard labeling for antihypertensive drugs except where differences are clearly supported by clinical data. After this guidance has been finalized, applicants will be encouraged to submit labeling supplements containing the new language.

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 labeling for cardiovascular outcome claims for drugs indicated to treat hypertension. 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. 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

III. 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 6, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–5083 Filed 3–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Revision to Existing System of Records; Revised

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notification of an Altered System of Records; revised.

SUMMARY: In accordance with the requirements of the Privacy Act, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to alter the system of records for the C.W. Bill Young Cell Transplantation Program. This system of records is required to comply with the implementation directives of Public Law 109–129. Records are used for the C.W. Bill Young Cell Transplantation Program's planning, implementation, evaluation, monitoring, and document storage purposes.

HRSA published in the **Federal Register** of August 17, 2007, a document concerning notice of a new system of records, 09–15–0068, C.W. Bill Young Cell Transplantation Program (FR. Doc. 07–4019). This document more fully explains the routine uses of records maintained in the system and amends the record retention and disposal policy. Accordingly, the notice is published below in its entirety, as amended.

DATES: Persons wishing to comment on this revised system of records notice may do so until April 14, 2008. Unless there is a further notice in the **Federal Register**, this revised system of records will become effective on April 14, 2008.

ADDRESSES: Please address comments to Health Resources and Services Administration Privacy Act Coordinator, Donn Taylor, 5600 Fishers Lane, Room 14A–20, Rockville, Maryland 20857; telephone (301) 443–0204. This is not a toll-free number. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, Division of Transplantation, HSB, HRSA, 5600 Fishers Lane, Room 12C–06, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Health Resources and Services Administration published in the **Federal Register** of August 17, 2007, notice of a new system of records, 09–15–0068, C.W. Bill Young Cell Transplantation Program. The Stem Cell Therapeutic and Research Act of 2005 (the Act) establishes the C.W. Bill Young Cell Transplantation Program (the Program) which maintains information related to patients in need of a blood stem cell transplant and potential adult volunteer blood stem cell donors who have agreed to be listed on the registry maintained by the Program. Additionally, the Program maintains information related to the outcomes of patients who have undergone blood stem cell transplantation.

The Stem Cell Therapeutic and Research Act of 2005 authorizes the C.W. Bill Young Cell Transplantation Program and provides for the collection, maintenance, and distribution of human blood stem cells for the treatment of patients and for research. The Program consists of four interrelated components each operated under a separate contract. The four components are: the Bone Marrow Coordinating Center; the Cord Blood Coordinating Center; the Office of Patient Advocacy/Single Point of Access; and the Stem Cell Therapeutic Outcomes Database. The contracts for operation of the Bone Marrow Coordinating Center, Cord Blood Coordinating Center, and Office of Patient Advocacy/Single Point of Access were awarded to the National Marrow Donor Program in September 2006. A single contract for the Stem Cell Therapeutic Outcomes Database was awarded to the Center for International Blood and Marrow Transplant Research (CIBMTR) at the Medical College of Wisconsin in September 2006 as well.

As identified by the Act, the Program is charged with: Operating a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients; operating a system for identifying, matching, and facilitating the distribution of donated umbilical cord blood units that are suitably matched to candidate patients; providing a means by which transplant physicians, other healthcare professionals, and patients can electronically search for and access all available adult marrow donors available through the Program; recruiting potential adult volunteer marrow donors; coordinating with other Federal programs to maintain and expand medical contingency response capabilities; carrying out informational and educational activities; providing patient advocacy services; providing case management services for potential donors; and collecting, analyzing, and publishing blood stem cell transplantation related data, including patient outcomes data, in a standardized electronic format. This system of records is required to comply with the implementation directives of the Act, Public Law 109–129. The records will be used for the C.W. Bill Young Cell Transplantation Program's planning, implementation, evaluation, monitoring, and document storage purposes.

Dated: February 19, 2008.

Elizabeth M. Duke,

Administrator.

09–15–0068

SYSTEM NAME:

C.W. Bill Young Cell Transplantation Program.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Data collected by the C.W. Bill Young Cell Transplantation Program (the Program) are maintained by the National Marrow Donor Program (NMDP) and the Medical College of Wisconsin, contractors for the Program. The Division of Transplantation within the