(1) The medical product industry (particularly the medical device industry) is focused on ensuring Year 2000 compliance. To dedicate computer personnel to totally revamp their computer systems to handle the new form would not be possible at this time because of the impact it would have on meeting absolute deadlines; and

(2) Given that the goal is for both the pharmaceutical and medical device industries to submit the majority of mandatory reports electronically, it would present a financial burden to revamp systems to accommodate a paper form that will be virtually obsolete in the future.

While the comments on the proposed revisions to the voluntary form were mainly favorable, the agency has decided to not revise either form at this time. This decision reflects both concern about the financial burden that would be placed on FDA if the voluntary form underwent revision, and the availability of other avenues by which use of the voluntary and mandatory forms can be optimized, namely appropriate revision of documents related to their completion.

Regarding voluntary reporting, updated instructions for completing the Form FDA 3500 were posted on the Internet on the MedWatch home page in December 1998, and are available by mail/fax upon request. Questions/comments about adverse event/product problem reporting received by the agency over time were used as a major focus for revising the instructions. This updating included such changes as incorporation of information designed to solicit information specific to special nutritional products (e.g., dietary supplements) and current Department of Health and Human Services names and definitions for race to facilitate reporting of this aspect of the medical history.

In the same vein, an omnibus entitled ''Guidance on How to Complete Form FDA 3500A'' for use by user facilities, distributors, importers, and manufacturers for mandatory adverse event and product problem reporting is being drafted. Also utilizing questions/comments about adverse event/product problem reporting received by the agency over time as a major focus for revision, the guidance will be designed to minimize possible ambiguity and maximize the utility of Form FDA 3500A as a tool for soliciting important safety-related information and data. It is planned that this guidance will replace instructions that are currently available.

As both the Forms FDA 3500 (instructions) and 3500A (guidance) can be updated periodically based on questions/comments from stakeholders and statutory/regulatory changes, changing the forms themselves is not seen as necessary at this point.

At such time it is decided to repropose revisions, FDA will consult all interested parties for input into the design.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center(s)[1] (21 CFR Section)	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
CBER/CDER					
Form 3500[2]	15,456	1	15,456	0.5	7,728
Form 3500A[3] (310.305, 312.32, 314.80, 314.98, and 600.80)	410	529.3	217,014	1	217,014
CDRH					
Form 3500[2]	2,789	1	2,789	0.5	1,395
Form 3500A[3] (part 803)	3,100	30.25	93,786	1	93,786
CFSAN					
Form 3500[2]	316	1	316	0.5	158
Form 3500A[3] (No mandatory requirements)	0	0	0	1	0
Total Hours					320,081
Form 3500[2]					9,281
Form 3500A[3]					310,800

[1] CBER (Center for Biologics Evaluation and Research), CDER (Center for Drug Evaluation and Research), CDRH (Center for Devices and Radiological Health), and CFSAN (Center for Food Safety and Applied Nutrition).

[2] Form FDA 3500 is for voluntary reporting.

[3] Form FDA 3500A is for mandatory reporting.

Note.—The figures in Table 1 of this document are based on actual calendar year 1998 reporting experience. It is assumed that the number of reports will remain stable.

The increase in reporting burden reflects a natural increase in the number of reports coming into the agency. As more medical products are approved by FDA and marketed, and as knowledge increases of the importance of notifying FDA when adverse events and product problems are observed, it can be expected that more reports will be submitted to the agency either directly (voluntary Form FDA 3500) or via the manufacturer/user-facility (mandatory Form FDA 3500A).

Dated: September 7, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–24309 Filed 9–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for

review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Organ Procurement and Transplantation Network (OPTN) Data System (OMB No. 0915–0157)—Revision

This is a request for revision of the data system for the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) and the following associated forms: (1) cadaver donor registration/referral; (2) living donor registration; (3) donor histocompatibility; (4) potential recipient form; (5) recipient histocompatibility; (6) transplant candidate registration; (7) thoracic organ recipient registration; (8) thoracic organ recipient follow-up; (9) kidney transplant recipient registration; (10) kidney transplant recipient follow-up form; (11) liver transplant recipient registration; (12) liver transplant recipient follow-up; (13) pancreas transplant recipient registration; (14) pancreas transplant recipient follow-up; (15) intestine transplant recipient registration; and (16) intestine transplant recipient follow-up. New forms are related to intestine transplants to collect data similar to other types of transplants.

The estimated respondent burden is as follows:

	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Cadaveric Registration or Referral	65	277	0.3	5,400
Living Donor Registration	687	7	0.2	920
Living Donor Follow-up	687	14	0.1	952
Donor Histocompatibility	159	75	0.1	1,200
Potential Recipient Form	65	385	0.3	7,500
Recipient Histocompatibility	159	157	0.1	2,500
Transplant Candidate Registration	687	114	0.2	15,600
Thoracic Registration	153	27	0.3	1,230
Thoracic Follow-up	153	144	0.2	4,400
Kidney Registration	252	58	0.3	4,380
Kidney Follow-up	252	500	0.2	25,200
Liver Registration	125	40	0.4	2,000
Liver Follow-up	125	192	0.3	7,200
Pancreas Registration	125	11	0.3	420
Pancreas Follow-up	125	56	0.2	1,400
Intestine Registration	33	3	0.2	20
Intestine Follow-up	33	6	0.2	40
Total	911	.....	.....	80,362

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC.

Dated: September 14, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–24428 Filed 9–17–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health; Notice of Listing of Members of the National Institutes of Health's Senior Executive Service Performance Review Board (PRB)

The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health's Senior Executive Service Performance Review Board. This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals, and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the NIH Performance Review Board, which oversees the evaluation of performance appraisals of NIH Senior Executive Service (SES) members:

Ruth L. Kirschstein, Chairperson
Wendy Baldwin
Colleen Barros
Marvin Cassman
Naomi Churchill-Earp
Robert Desimone
Stephen Ficca
Michael Gottesman
Barry Hoffer
Anthony Itteilag
Alan Leshner
Yvonne Maddox
Louise Ramm

For further information about the NIH Performance Review Board, contact the Office of Human Resource Management, Senior and Scientific Employment Division, National Institutes of Health, Building 31/B3C08, Bethesda, Maryland 20892, telephone (301) 496–1443 (not a toll-free number).

Dated: September 9, 1999.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 99–24377 Filed 9–17–99; 8:45 am]

BILLING CODE 4140–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a Telephone Conference Call meeting of the Center for Substance Abuse Prevention (CSAP) National Advisory Council September 1999.

The agenda will include the review, discussion and evaluation of individual grant applications. Therefore this