

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
210 and 211	285	1	285	.25	71.25
Total					71.25

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

Dated: December 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0220]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and "Lookback"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and 'Lookback'" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of October 24, 2005 (70 FR 61447), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0116. The approval expires on December 31, 2008. A copy of the supporting statement for this information collection is available

on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

Translational Research Working Group Public Comment Period

AGENCY: National Cancer Institute (NCI), National Institutes of Health (NIH), Department of Health and Human Services (DHHS).

ACTION: Request for public comment.

SUMMARY: The Translational Research Working Group (TRWG), a broad panel including advocates, researchers from academia, industry representatives, and government officials, was established in early 2005 to evaluate the status of the National Cancer Institute's (NCI) intramural and extramural investment in translational research in order to develop recommendations on ways to coordinate and optimally integrate activities. The TRWG is also charged with developing implementation strategies that will enable the scientific community and NCI leadership to appropriately prioritize its translational research opportunities. Recommendations will be made to the National Cancer Advisory Board by early 2007. To assist in its future planning efforts, TRWG is asking public stakeholders in the translational research enterprise for feedback on some of the key questions facing the panel and insights on how to proceed.

DATES: The TRWG public comment period will run from December 20, 2005 to January 20, 2006.

ADDRESSES: Comments may be submitted electronically at the TRWG Web site: <http://www.cancer.gov/trwg/>.

SUPPLEMENTARY INFORMATION:

Background

The National Cancer Institute is committed to speeding the development of new diagnostic tests, cancer treatments, and other interventions that benefit people with cancer and people at risk for cancer. Such development relies on strong translational research collaborations between basic and clinical scientists to generate novel approaches. Currently, NCI supports a variety of projects that build this bridge between basic science and patient care.

Over the next year, the Translational Research Working Group (TRWG) will review NCI's current intramural and extramural translational research portfolio (within the scope of the TRWG mission), facilitate broad community input, invite public comment, and recommend ways to improve and integrate efforts. The ultimate goal is to accelerate progress toward improving the health of the nation and cancer patient outcomes.

Request for Comments

To better understand the different viewpoints in the cancer research community, and to develop and reflect a common understanding about the challenges and opportunities in translational research, TRWG seeks input on six important areas:

- Barriers to/Incentives for Translational Research.
- Prioritization.
- Funding.
- System Organization.
- Facilities/Technologies.
- Manpower/Training.

Dated: December 22, 2005.

Ernest Hawk,

Director, Office of Centers, Training and Resources, National Cancer Institute, National Institutes of Health.

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