

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01 N-01321

DMB

Display Date	10-12-01
Publication Date	10-15-01
Certifier	<i>[Signature]</i>

**Agency Information Collection Activities; Announcement of OMB Approval;
Protection of Human Subjects, Recordkeeping and Reporting Requirements for
Institutional Review Boards**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and **Drug** Administration (FDA) is announcing that a collection of information entitled "Protection. of Human Subjects, Recordkeeping and Reporting Requirements for Institutional Review Boards," has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 the **Federal Register** of March 30, 2001 (66 FR 17427), 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 0910-0130. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: 10/5/01

October 5, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

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