

for the entire 2001 public education campaign.

As a Congressional setaside, this one-year project is being funded noncompetitively. The organization has unique experience to conduct a national public education campaign to strengthen responsible and committed fatherhood. The cost of this one-year project is \$500,000.

FOR FURTHER INFORMATION CONTACT: Ken Maniha, Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Phone: 202-401-5372.

Dated: March 29, 2001.

Howard Rolston,

Director, Office of Planning, Research and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1449]

Agency Information Collection Activities; Announcement of OMB Approval; Changes to an Approved NDA or ANDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Changes to an Approved NDA or ANDA" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 December 21, 2000 (65 FR 80440), 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 0910-0431. The approval expires on March 31, 2004. A copy of the supporting statement for this

information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: March 29, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Studies of Adverse Effects of Marketed Drugs; Availability of Grants (Cooperative Agreements); Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, is announcing the anticipated availability of funds for cooperative agreements to study adverse effects of drugs marketed in the United States and its territories. Subject to the availability of fiscal year 2002 funds, FDA anticipates that approximately \$900,000 will be available. FDA anticipates making up to three awards, each for up to \$300,000 per year (direct and indirects costs) for general databases that cover U.S. patients only, cover multiple States across the United States, had more than 1.5 million enrolled patients on December 31, 2000, and have the demonstrated ability to obtain paper copies of anonymized patient medical records.

Support for these agreements may be for up to 3 years subject to availability of future funds and satisfactory performance during the preceding year. The purpose of these agreements is to conduct drug safety analysis to the benefit of the public's health; respond expeditiously to urgent public safety concerns; provide a mechanism for collaborative pharmacoepidemiological research designed to test hypotheses, particularly those arising from suspected adverse reactions reported to FDA; and enable rapid access to U.S. population-based data sources to ensure public safety when necessary. **DATES:** Submit applications by June 4, 2001.

ADDRESSES: Application kits are available from, and completed applications should be submitted to Rosemary T. Springer, Division of Contracts and Procurement Management (HFA-520), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7182.

Note: Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857. Please DO NOT send applications to the Center for Scientific Review (CSR), National Institutes of Health (NIH). Applications mailed to CSR and not received by FDA in time for orderly processing will be returned to the applicant without consideration. Application forms can also be found at <http://www.nih.gov/grants/phs398/forms-toc.html>.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Rosemary T. Springer (address above).

Regarding the programmatic aspects of this notice: David J. Graham, Office of Postmarketing Drug Risk Assessment (HFD-400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3238.

SUPPLEMENTARY INFORMATION: As stated later in this document, funding of the second and third years will be contingent upon: (1) Investigator's demonstrated success collaborating with FDA scientists, as well as with other investigators funded by this cooperative agreement program. Such demonstration may include suggestions for and design of a study, analysis of data sets, and publication of results among FDA and cooperative agreement investigators; and (2) the availability of Federal fiscal year appropriations.

It is determined that these cooperative agreements are exempt from the protection of human subjects requirements in accordance with 45 CFR part 46.

FDA's authority to fund research projects is set out in section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103. Applications submitted under this program are not subject to the requirements of Executive Order 12372.

The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and to