

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Carryover and Reallotment	177	1	3	531

Estimated Total Annual Burden Hours: 531.

In compliance with the requirements of section 3506(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 Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. e-mail: grjohnson@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: September 23, 2004.
Robert Sargis,
Reports Clearance Officer.
 [FR Doc. 04-21787 Filed 9-28-04; 8:45 am]
BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Guidance for the Tribal Temporary Assistance for Needy Families (TANF) Program.

OMB No.: 0970-0157.

Description: 42 U.S.C. 612 (Section 412 of the Social Security Act) requires each Indian tribe that elects to administer and operate a TANF program to submit a TANF Tribal Plan. The TANF Tribal Plan is a mandatory statement submitted to the Secretary by the Indian tribe, which consists of an outline of how the Indian tribe's TANF program will be administered and operated. It is used by the Secretary to determine whether the plan is approvable and to determine that the Indian tribe is eligible to receive a TANF assistance grant. It is also made available to the public.

Respondents: Indian Tribes applying to operate a TANF program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request for State Data Needed to Determine the Amount of a Tribal Family Assistance Grant	20	1	60	1200

Estimated Total Annual Burden Hours: 1200

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: grjohnson@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written

comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: Katherine_T._Astrich@omb.eop.gov.

Dated: September 22, 2004.
Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0565]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Generic Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Generic Food and Drug Administration Rapid Response Surveys" has been

approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 6, 2004, (69 FR 25404), 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 0910-0500. The approval expires on February 28, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: September 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-21748 Filed 9-28-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0017]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adverse Event Pilot Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Adverse Event Pilot Program for Medical Devices" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 14, 2004 (69 FR 33034), 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 0910-0471. The approval expires on September 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: September 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-21750 Filed 9-28-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E-0033]

Determination of Regulatory Review Period for Purposes of Patent Extension; DERMAGRAFT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DERMAGRAFT and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions 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.fda.gov/docket/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Claudia V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive,

or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device DERMAGRAFT. DERMAGRAFT is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than 6-weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. DERMAGRAFT should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Dermagraft (U.S. Patent No. 4,963,489) from Advanced Tissue Sciences, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 10, 2003, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of DERMAGRAFT represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for DERMAGRAFT is 4,050 days. Of this time, 3,650 days occurred during the testing phase of the regulatory review period, while 400 days occurred during the approval phase. These periods of