Dated: January 15, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–1689 Filed 1–23–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02E01]

Medical Monitoring for New York Personnel Engaged in Emergency Response Activities Related to the Disaster of September 11, 2001; Notice of Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the award of funds for a cooperative agreement program for Medical Monitoring for New York Personnel Engaged in Emergency Response Activities Related to the Disaster of September 11, 2001. The purpose of the program is to provide medical monitoring for New York City Fire Department and New York State Personnel who may have been exposed to hazardous substances while providing emergency response services as a result of the disaster of September 11, 2001. This program addresses the ''Healthy People 2010'' focus areas Environmental Health and Public Health Infrastructure.

B. Eligible Applicant

Eligible applicants are Health Research, Inc./New York State Department of Health and New York City Fire Department. No other applications were solicited. New York State has received a Presidential declaration of disaster.

This project is authorized by H.R. 2888, 2001 Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States.

C. Availability of Funds

Approximately $4,801,550 is available to fund one award to New York City Fire Department, and approximately $2,406,000 is available to fund one award to Health Research, Inc./New York State Department of Health. It is expected that each award will be made for a 12-month budget period. As long as funds are directed for these applicants, continuation funding will be made available for up to 5 years. Funding estimates may vary and are subject to change.

D. Where To Obtain Additional Information

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sharon Robertson, Lead Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: (770) 488–2740, E-mail address: *sqr2@cdc.gov.*

For program technical assistance, contact: Ron Burger, Public Health Advisor, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE (MS F–38) Atlanta, GA 30341–3724, Telephone number: (404) 488–4024, E-mail address: *rburger@cdc.gov.*

Dated: January 17, 2002.

Rebecca B. O'Kelley,

Chief, International Grants and Contracts Branch, Procurement and Grants Office, Center for Disease Control and Prevention (CDC).

[FR Doc. 02–1717 Filed 1–23–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control; Special Emphasis Panel (SEP): Grants for Education Programs in Occupational Safety and Health, Program Announcement #02001

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grants for Education Programs in Occupational Safety and Health, Program Announcement #02001.

Times and Dates:

7 p.m.–7:25 p.m., February 17, 2002 (Open)

7:30 p.m.–10:15 p.m., February 17, 2002 (Closed)

8 a.m.–6 p.m., February 18, 2002 (Closed)

8 a.m.–6:30 p.m., February 19, 2002 (Closed)

8 a.m.–1 p.m., February 20, 2002 (Closed)

Place: Trade Winds Sandpiper Hotel, 6000 Gulf Boulevard, St. Pete Beach, Florida 33706.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Deputy Director for Program Management, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #02001.

CONTACT PERSON FOR MORE INFORMATION: Bernadine Kuchinski, Ph.D., Occupational Health Consultant, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE, M/S D40, telephone (404) 639–3342.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 16, 2002.

Alvin Hall,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–1718 Filed 1–23–02; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Announcement of Office of Management and Budget (OMB) Control Numbers for Agency Information Collections Approved Under the Paperwork Reduction Act of 1995

AGENCY: Centers for Medicare and Medicaid Services, HHS.

This notice announces and displays OMB control numbers for Centers for Medicare and Medicaid Services (CMS) information collections that have been approved by OMB.

Under OMB's regulations implementing the Paperwork Reduction Act (PRA), 44 U.S.C. 3501, each agency that proposes to collect information must submit its proposal for OMB review and approval in accordance with 5 CFR part 1320. Once OMB has

approved an agency's proposed collection of information and issues a control number, the agency must display the control number.

OMB regulations provide for alternative methods of displaying OMB control numbers. In the case of collections of information published in regulations, display is to be ''provided in a manner that is reasonably calculated to inform the public.'' To meet this requirement an agency may display such information in the **Federal Register** by publishing such information in the preamble or the regulatory text, or in a technical amendment to the regulation, or in a separate notice announcing OMB approval of the collection of information.

To comply with this requirement, CMS has chosen to publish this notice announcing OMB approval of the collections of information published in regulations. As stated above, this notice announces and displays the assigned OMB control numbers for CMS's information collections that have been approved by OMB.

	OMB control Nos.
42 CFR:	
405.262	0938–0267
405.371	0938–0600
405.376	0938–0270
405.378	0938–0600
405.410	0938–0730
405.430, 405.435, 405.440, 405.445, 405.455	0938–0730
405.711	0938–0045
405.807	0938–0033
405.821	0938–0034
405.2100–405.2171	0938–0386
405.2110, 405.2112	0938–0657, & 0658
405.2133	0938–0046
405.2135–405.2171	0938–0360
405.2470	0938–0155
406.7	0938–0251
406.13	0938–0080
406.15	0938–0501
406.28	0938–0025 & 0787
407.10, 407.11	0938–0245
407.18	0938–0679
407.27	0938–0025 & 0787
407.40	0938–0035
408.6	0938–0041
409.40–409.50	0938–0357
410.1	0938–0679
410.2	0938–0770
410.32	0938–0685
410.33	0938–0721
410.36	0938–0357
410.38	0938–0534
410.40	0938–0042
410.61	0938–0730
410.71	0938–0685
410.141–410.145	0938–0818
410.170	0938–0357
411.1	0938–0846
411.4–411.15	0938–0357
411.20–411.206	0938–0565
411.350–411.357	0938–0846
411.370—411.389	0938–0714
411.404—411.406	0938–0465, 0781 & 0692
411.408	0938–0566
412	0938–0842
412.20–412.32	0938–0358
412.40–412.52	0938–0359
412.42	0938–0692
412.44, 412.46	0938–0445
412.92	0938–0477
412.105	0938–0456
412.106	0938–0691
412.116	0938–0269
412.256	0938–0573
413	0938–0842
413.17	0938–0202 & 0685
413.20	0938–0202, 0236 & 0600
413.20, 413.24	0938–0022, 0037, 0050, 0102, 0107, 0236, 0301, 0463, 0511 & 0758
413.64	0938–0269

	OMB control Nos.
413.106	0938–0022
413.170	0938–0296
413.343	0938–0739
414.40	0938–0008
414.63	0938–0818
414.330	0938–0372
415.50, 415.55, 415.60, 415.70	0938–0301
415.110	0938–0730
415.150, 415.152, 415.160, 415.162	0938–0301
416.1–416.150	0938–0266
416.44	0938–0242
417.126	0938–0469 & 0732
417.143	0938–0470
417.162	0938–0469
417.408	0938–0470
417.436	0938–0610
417.440	0938–0692
417.470	0938–0732
417.478	0938–0469
417.479, 417.500	0938–0700
417.801	0938–0610
417.800–417.840	0938–0768
418.1–418.405	0938–0313& 0379
418.22, 418.24, 418.28, 418.56, 418.58, 418.70, 418.83, 418.96, 418.100	0938–0302
418.100	0938–0242
420.200–420.206	0938–0086
421.100	0938–0357
421.310, 421.312	0938–0723
422.1–422.10, 422.50–422.80, 422.100–422.132, 422.300–422.312, 422.400–422.404, 422.560–422.622	0938–0763
422.1–422.700	0938–0753
422.64, 422.111, 422.560—422.622	0938–0778
422.152	0938–0701 & 0840
422.208, 422.210	0938–0700
422.300–422.312	0938–0742
422.370–422.378	0938–0722
422.568	0938–0829
422.620	0938–0692
424.5	0938–0534 & 0279
424.20	0938–0454
424.22	0938–0357, 0489 & 0846
424.24	0938–0730
424.32	0938–0008 & 0739
424.44	0938–0008
424.57	0938–0717, 0749, & 0685
424.73, 424.80	0938–0685
424.103	0938–0023
424.123	0938–0484
424.124	0938–0042
426.102–426.104	0938–0526
430.10	0938–0673
430.10–430.20	0938–0193
430.12	0938–0610
430.20	0938–0610
430.30	0938–0101
431.1–431.865	0938–0062
431.17	0938–0467
431.107	0938–0610
431.306	0938–0467
431.630	0938–0445
431.636	0938–0841
431.800	0938–0300
431.800–431.820	0938–0144
431.800–431.865	0938–0146, 0147, & 0246
433.68, 433.74	0938–0618
433.138	0938–0502
434.28	0938–0610
434.44, 434.67, 434.70	0938–0700
435.1–435.1011	0938–0062
435.910, 435.920, 435.940–435.960	0938–0467
438.364	0938–0786
440.1–440.270	0938–0062
440.30	0938–0685

	OMB control Nos.
440.167	0938–0193
440.180	0938–0272, & 0449
441.16	0938–0713
441.60	0938–0354
441.152	0938–0754
441.300–441.305	0938–0272
441.300–441.310	0938–0449
442.1–442.119	0938–0062
447.31	0938–0287
447.53	0938–0429
447.254	0938–0784
447.272	0938–0618 & 0855
447.280	0938–0624
447.321	0938–0855
447.500–447.542	0938–0676
447.550	0938–0676
455.100–455.106	0938–0086
456.654	0938–0445
456.700, 456.705, 456.709, 456.711, 456.712	0938–0659
457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, 457.1180.	0938–0841
460.12, 460.22, 460.30, 460.32, 460.52, 460.60, 460.68, 460.70, 460.72, 460.74, 460.80, 460.82, 460.98, 460.100, 460.102, 460.104, 460.106, 460.110, 460.112, 460.116, 460.118, 460.120, 460.122, 460.124, 460.132, 460.152, 460.154, 460.156, 460.160, 460.164, 460.168, 460.172, 460.190, 460.196, 460.200, 460.202, 460.204, 460.206, 460.208, 460.210.	0938–0790
466.71, 466.73, 466.74, 466.78	0938–0445
466.78	0938–0692
473.18, 473.34, 473.36, 473.42	0938–0443
476.104, 476.105, 476.116, 476.134	0938–0426
482.1–482.66	0938–0380
482.2–482.57	0938–0382
482.12, 482.22	0938–0328
482.27	0938–0328
482.41	0938–0242
482.30, 482.41, 482.43, 482.53, 482.56, 482.57	0938–0328
482.45	0938–0810
482.60—482.62	0938–0378 & 0328
482.66	0938–0328, & 0624
483.10	0938–0610
483.270	0938–0242
483.350–483.376	0938–0833
483.400–483.480	0938–0062
483.470	0938–0242
484.1–484.52	0938–0365
484.10	0938–0610 & 0781
484.10–484.52	0938–0355
484.11	0938–0761
484.12	0938–0685
484.18	0938–0357
484.20	0938–0761
484.55	0938–0760
484.220	0938–0760
485.56, 485.58, 485.60, 485.64, 485.66	0938–0267
485.701–485.729	0938–0065, & 0273
486.100—486.110	0938–0027
486.104, 486.106, 486.110	0938–0338
486.301–486.325	0938–0512, & 0688
488.4–488.9	0938–0690
488.18	0938–0391, & 0667
488.26	0938–0391
488.28	0938–0391
488.60	0938–0360
488.201	0938–0690
489	0938–0832
489.20	0938–0214, 0667, & 0692
489.21	0938–0357
489.24	0938–0667
489.27	0938–0692
489.32, 489.34	0938–0692
489.66, 489.67	0938–0713
489.102	0938–0610
491.1–491.11	0938–0074

	OMB control Nos.
491.3, 491.8	0938–0792
491.9	0938–0334
493.1–493.2001	0938–0151, 0544, 0581, 0599, 0612, 0650, & 0653
493.551–493.557	0938–0686
493.1269—493.1285	0938–0170
493.1840	0938–0655
498.40–498.95	0938–0486, & 0567
1003.100, 1003.101, 1003.103	0938–0700
1004.40, 1004.50, 1004.60, 1004.70	0938–0444
45 CFR:	
5b	0938–0734
146	0938–0702
146.121	0938–0819
146.141	0938–0827
148	0938–0703 & 0797

Dated: January 15, 2002.

John P. Burke III,

CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 02–1686 Filed 1–23–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0851]

Determination of Regulatory Review Period for Purposes of Patent Extension; T-Scan 2000

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for T-Scan 2000 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 Commissioner 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 Commissioner 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 T-Scan 2000. T-Scan 2000 is intended for use as an adjunct to mammography in patients who have equivocal mammographic findings within ACR–BI–RADS categories 3 and 4. In particular, it is not intended for use in cases with clear mammographic or non-mammographic indications for biopsy. This device provides the radiologist with additional information to guide a biopsy recommendation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for T-Scan 2000 (U.S. Patent No. 4,291,708) from Transcan Research and Development Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 13, 2000, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of T-Scan 2000 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 T-Scan 2000 is 1,595 days. Of this time, 964 days occurred during the testing phase of the regulatory review period, while 631 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: December 5, 1994. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective December 5, 1994.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: July 25, 1997. FDA has verified the applicant's claim that the premarket approval application (PMA) for T-Scan 2000 (PMA P970033) was initially submitted July 25, 1997.

3. *The date the application was approved*: April 16, 1999. FDA has