These collaborative activities can profoundly change the focus and activities of the South African National TB Control Program and improve TB treatment and control programs and related prevention efforts in South Africa.

B. Eligible Applicants

Assistance will be provided only to the Medical Research Council (MRC) of South Africa. No other applications will be solicited. MRC will support and ensure implementation of tuberculosis (TB) control activities that are designed to develop, establish, and coordinate systems and procedures to address the obstacles to achieving control of tuberculosis and multi-drug tuberculosis (MDR–TB) in South Africa.

MRC is the most appropriate and qualified agency to conduct the activities under this cooperative agreement because:

1. The MRC is uniquely positioned, in terms of legal authority, ability, track record, and credibility in South Africa to develop and support TB control activities in both public and non-governmental organization sites throughout the country.

2. The MRC has already established mechanisms to develop and implement TB treatment services in South Africa, enabling it to immediately become engaged in the activities listed in this announcement.

3. The purpose of the announcement is to build upon the existing framework of TB control activities that the MRC has developed or initiated.

4. The MRC has been mandated by the South African government to coordinate and implement TB treatment and control activities including MDR–TB within the country.

5. MRC has a unique and unparalleled involvement with the Ministry of Health's National Tuberculosis Control Program (NTP) and the South African National Tuberculosis Association (SANTA) based on a history of collaboration.

6. MRC coordinates the research and development activities for the Global Alliance for TB Drug Development in the search for a better, more effective and affordable cure for TB that is shorter, equally effective against susceptible and drug-resistant TB, accessible to the populations that need it most, and be on the market in less than 10 years.

C. Funds

Approximately $307,000 is being awarded in FY 2002. The award will be made by July 1, 2002, for a 12-month budget period within a project period of up to five years.

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:

Angelia D. Hill, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, MS E–09, Atlanta, GA 30341–4146, Telephone: (770) 488–2785, FAX: (770) 488–2688, E-mail: *aph8@cdc.gov.*

Michael Qualls, Deputy Associate Director, International Activities, Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention Centers for Disease Control and Prevention (CDC), 1600 Clifton Road Mailstop E–10, Atlanta, GA 30333, Telephone 404–639–8488, Email address: *muq1@cdc.gov.*

Dated: August 20, 2002.

Sandra R. Manning, CGFM,

Director, Procurement and Grants Office, Centers for Disease Control & Prevention.

[FR Doc. 02–21731 Filed 8–26–02; 8:45 am]

BILLING CODE 4163–18–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.

42 CFR	OMB Control Nos.
405.262	0938–0267
405.371	0938–0600
405.376	0938–0270
405.378	0938–0600
405.410	0938–0730
405.430, .435, .440, .445, .455.	0938–0730
405.711	0938–0045
405.807	0938–0033
405.821	0938–0034
405.2100–.2171	0938–0386
405.2110, 405.2112	0938–0657 & 0658
405.2133	0938–0046
405.2135–.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–.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–.145	0938–0818
410.170	0938–0357
411.1	0938–0846
411.4–.15	0938–0357
411.20–411.206	0938–0565
411.25	0938–0214
411.350–.357	0938–0846
411.370–411.389	0938–0714
411.404–.406	0938–0465, 0781 & 0692
411.408	0938–0566
412	0938–0842

42 CFR	OMB Control Nos.
412.20–.32	0938–0358
412.40–.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
413.106	0938–0022
413.170	0938–0296
413.337	0938–0739 & 0872
413.343	0938–0739
414.40	0938–0008
414.63	0938–0818
414.330	0938–0372
415.50, .55, .60, .70	0938–0301
415.110	0938–0730
415.150, .152, .160, .162	0938–0301
416.1–.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–.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
419	0938–0857 & 0860
419.43	0938–0802
420.200–.206	0938–0086
421.100	0938–0357
421.310, 421.312	0938–0723
422.1–.10, 422.50–.80, 422.100–.132, 422.300–.312, 422.400–.404, 422.560–.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–.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–.960.	0938–0467
438.364	0938–0786
440.1–.270	0938–0062
440.30	0938–0685
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–.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–.542	0938–0676
447.550	0938–0676
455.100–.106	0938–0086
456.654	0938–0445
456.700, 456.705, 456.709, 456.711, 456.712.	0938–0659
457.50, .60, .70, .340, .350, .431, .440, .525, .560, .570, .740, .750, .810, .940, .945, .965, .985, .1005, .1015, .1180.	0938–0841
460.12, .22, .30, .32, .52, .60, .68, .70, .72, .74, .80, .82, .98, .100, .102, .104, .106, .110, .112, .116, .118, .120, .122, .124, .132, .152, .154, .156, .160, .164, .168, .172, .190, .196, .200, .202, .204, .206, .208, .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–.66	0938–0380
482.2–.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–.62	0938–0378 & 0328
482.66	0938–0328 & 0624
483.10	0938–0610
483.20	0938–0739 & 0872
483.270	0938–0242
483.350–.376	0938–0833
483.400–.480	0938–0062
483.470	0938–0242
484.1–.52	0938–0365
484.10	0938–0610 & 0781
484.10–.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–.729	0938–0065 & 0273
486.100–.110	0938–0027
486.104, 486.106, 486.110	0938–0338
486.301–.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
489.2	0938–0214
489.20	0938–0214, 0667 & 0692
489.21	0938–0357
489.24	0938–0667
489.27	0938–0692
489.32, 489.34	0938–0692

42 CFR	OMB Control Nos.
489.66, 489.67	0938–0713
489.102	0938–0610
491.1–.11	0938–0074
491.3, 491.8	0938–0792
491.9	0938–0334
491.11	0938–0792
493.1–.2001	0938–0151, 0544, 0581, 0599, 0612, 0650 & 0653
493.551–.557	0938–0686
493.1269–.1285	0938–0170
493.1840	0938–0655
498.40–.95.	0938–0486 & 0567
1003.100, 1003.101, 1003.103.	0938–0700
1004.40, 1004.50, 1004.60, 1004.70.	0938–0444

45 CFR	OMB. Control Nos
5b	0938–0734
146	0938–0702
146.121	0938–0819
146.141	0938–0827
148	0938–0703 & 0797
162	0938–0866

Dated: August 20, 2002.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 02–21711 Filed 8–26–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0007]

Agency Information Collection Activities; Announcement of OMB Approval; CGMP Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''CGMP Regulations for Finished Pharmaceuticals'' 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 May 16, 2002 (67 FR 34939), 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 0910–0139. This approval expires on August 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 21, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–21735 Filed 8–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications (Catalog of Federal Domestic Assistance No. 93.103)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes to its Office of Orphan Products Development (OPD) grant program for fiscal year (FY) 2003. This announcement supercedes the previous announcement of this program, which was published in the **Federal Register** on August 27, 2001.

DATES: The application receipt dates are October 16, 2002, and April 2, 2003.

ADDRESSES: Application requests and completed applications should be submitted to Maura Stephanos, Grants Management Specialist, Grants Management Staff, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183, FAX 301–827–7101, e-mail: mstepha1@oc.fda.gov. Applications that are hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857. Applications may also be obtained from the OPD on the Internet at http://www.fda.gov/orphan or at http://grants.nih.gov/grants/funding/phs398/phs398.html. Note: Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management issues of this notice: Maura Stephanos (see **ADDRESSES**).

Regarding the programmatic issues of this notice: Debra Y. Lewis, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 15A–08, Rockville, MD 20857, 301–827–3666, FAX 301–827–0017, e-mail: dlewis@oc.fda.gov.

SUPPLEMENTARY INFORMATION: All studies of new drug and biological products must be conducted under the FDA's investigational new drug (IND) procedures and studies of medical devices must be conducted under the investigational device exemption (IDE) procedures. Studies of approved products to evaluate new orphan indications are acceptable; however, these must also be conducted under an IND or IDE to support a change in labeling. The study protocol proposed in the grant application must be under an active IND or IDE (not on clinical hold) to qualify the application for scientific and technical review. (See Program Review Criteria for important information about the IND/IDE status of products to be studied under these grants.)

Except for medical foods that do not need premarket approval, FDA will only consider awarding grants to support premarket clinical studies to find out whether the products are safe and effective for approval under section 301 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*) or under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262).

FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act. FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103. 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.