

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.	42 CFR	OMB Control Nos.	42 CFR	OMB Control Nos.
412.20-.32	0938-0358	422.370-422.378	0938-0722	457.50, .60, .70, .340, .350,	0938-0841
412.40-.52	0938-0359	422.568	0938-0829	.431, .440, .525, .560, .570,	
412.42	0938-0692	422.620	0938-0692	.740, .750, .810, .940, .945,	
412.44, 412.46	0938-0445	424.5	0938-0534 &	.965, .985, .1005, .1015,	
412.92	0938-0477		0279	.1180.	
412.105	0938-0456	424.20	0938-0454	460.12, .22, .30, .32, .52, .60,	0938-0790
412.106	0938-0691	424.22	0938-0357,	.68, .70, .72, .74, .80, .82,	
412.116	0938-0269		0489 &	.98, .100, .102, .104, .106,	
412.256	0938-0573		0846	.110, .112, .116, .118, .120,	
413	0938-0842	424.24	0938-0730	.122, .124, .132, .152, .154,	
413.17	0938-0202 &	424.32	0938-0008 &	.156, .160, .164, .168, .172,	
	0685		0739	.190, .196, .200, .202, .204,	
413.20	0938-0202,	424.44	0938-0008	.206, .208, .210.	
	0236 &	424.57	0938-0717,	466.71, 466.73, 466.74,	0938-0445
	0600		0749, &	466.78.	
413.20, 413.24	0938-0022,		0685	466.78.	0938-0692
	0037,	424.73, 424.80	0938-0685	473.18, 473.34, 473.36,	0938-0443
	0050,	424.103	0938-0023	473.42.	
	0102,	424.123	0938-0484	476.104, 476.105, 476.116,	0938-0426
	0107,	424.124	0938-0042	476.134.	
	0236,	426.102-426.104	0938-0526	482.1-.66	0938-0380
	0301,	430.10	0938-0673	482.2-.57	0938-0382
	0463, 0511	430.10-20	0938-0193	482.12, 482.22	0938-0328
	& 0758	430.12	0938-0610	482.27	0938-0328
413.64	0938-0269	430.20	0938-0610	482.41	0938-0242
413.106	0938-0022	430.30	0938-0101	482.30, 482.41, 482.43,	0938-0328
413.170	0938-0296	431.1-431.865	0938-0062	482.53, 482.56, 482.57.	
413.337	0938-0739 &	431.17	0938-0467	482.45	0938-0810
	0872	431.107	0938-0610	482.60-.62	0938-0378 &
413.343	0938-0739	431.306	0938-0467	482.66	0328
414.40	0938-0008	431.630	0938-0445	483.10	0938-0328 &
414.63	0938-0818	431.636	0938-0841	483.20	0624
414.330	0938-0372	431.800	0938-0300		0938-0610
415.50, .55, .60, .70	0938-0301	431.800-431.820	0938-0144	483.270	0938-0739 &
415.110	0938-0730	431.800-431.865	0938-0146,	483.350-.376	0872
415.150, .152, .160, .162	0938-0301		0147, &	483.400-.480	0938-0242
416.1-.150	0938-0266	433.68, 433.74	0246	483.470	0938-0242
416.44	0938-0242	433.138	0938-0618	484.1-.52	0938-0365
417.126	0938-0469 &	434.28	0938-0502	484.10	0938-0610 &
	0732	434.44, 434.67, 434.70	0938-0610	484.10-.52	0781
417.143	0938-0470	435.1-435.1011	0938-0700	484.11	0938-0355
417.162	0938-0469	435.910, 435.920, 435.940-	0938-0062	484.12	0938-0761
417.408	0938-0470	.960.	0938-0467	484.18	0938-0685
417.436	0938-0610	438.364	0938-0786	484.20	0938-0357
417.440	0938-0692	440.1-.270	0938-0062	484.55	0938-0761
417.470	0938-0732	440.30	0938-0685	484.220	0938-0760
417.478	0938-0469	440.167	0938-0193	485.56, 485.58, 485.60,	0938-0267
417.479, 417.500	0938-0700	440.180	0938-0272, &	485.64, 485.66.	
417.801	0938-0610		0449	485.701-.729	0938-0065 &
417.800-.840	0938-0768	441.16	0938-0713	486.100-.110	0273
418.1-418.405	0938-0313 &	441.60	0938-0354	486.104, 486.106, 486.110	0938-0027
	0379	441.152	0938-0754	486.301-.325	0938-0338
418.22, 418.24, 418.28,	0938-0302	441.300-441.305	0938-0272		0938-0512 &
418.56, 418.58, 418.70,		441.300-441.310	0938-0449	488.4-488.9	0688
418.83, 418.96, 418.100.		442.1-.119	0938-0062	488.18	0938-0690
418.100	0938-0242	447.31	0938-0287		0938-0391 &
419	0938-0857 &	447.53	0938-0429	488.26	0667
	0860	447.254	0938-0784	488.28	0938-0391
419.43	0938-0802	447.272	0938-0618 &	488.60	0938-0360
420.200-.206	0938-0086		0855	488.201	0938-0690
421.100	0938-0357	447.280	0938-0624	489	0938-0832
421.310, 421.312	0938-0723	447.321	0938-0855	489.2	0938-0214
422.1-.10, 422.50-.80,	0938-0763	447.500-.542	0938-0676	489.20	0938-0214,
422.100-.132, 422.300-		447.550	0938-0676		0667 &
.312, 422.400-.404,		455.100-.106	0938-0086	489.21	0692
422.560-.622.		456.654	0938-0445	489.24	0938-0357
422.1-422.700	0938-0753	456.700, 456.705, 456.709,	0938-0659	489.27	0938-0667
422.64, 422.111, 422.560-	0938-0778	456.711, 456.712.		489.32, 489.34	0938-0692
422.622.					0938-0692
422.152	0938-0701 &				
	0840				
422.208, 422.210	0938-0700				
422.300-422.312	0938-0742				

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](mailto: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](mailto: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.